



FEED THE FUTURE
The U.S. Government's Global Hunger & Food Security Initiative



Feed the Future
BIOTECHNOLOGY POTATO PARTNERSHIP
FINAL PROJECT REPORT



FINAL PROJECT REPORT FY2016-2021

Feed the Future Biotechnology Potato Partnership

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COUNTRIES WHERE THE PROJECT WORKS:

Bangladesh, Indonesia, and United States

PROGRAM PARTNERS:



Acronyms

ABSPII	Agricultural Biotechnology Support Project II
AOR	Agreement Officer Representative
BAU	Bangladesh Agricultural University
BARC	Bangladesh Agricultural Research Council
BARI	Bangladesh Agricultural Research Institute
BBPJTF	Bangladesh Biotechnology Partnership Joint Task Force
BCC	Biosafety Core Committee
BPP	Feed the Future Biotechnology Potato Partnership
BTT	Biosafety Technical Team
CARE-IPB	Centre for Dispute Resolutions, Regulation & Policy Analysis and Community Empowerment at Bogor Agricultural University
CFT	Confined Field Trial
CIP	International Potato Center
DAP	Days After Planting
DDL	Development Data Library
EMMP	Environmental Management and Mitigation Plan
FFB	Farming Future Bangladesh
FTF	Feed the Future
FY	Fiscal Year
FY2016	Fiscal Year One: October 1, 2015 – September 30, 2016
FY2017	Fiscal Year Two: October 1, 2016 – September 30, 2017
FY2018	Fiscal Year Three: October 1, 2017 – September 30, 2018
FY2019	Fiscal Year Four: October 1, 2019 – September 30, 2019
FY2020	Fiscal Year Five: October 1, 2019 – September 30, 2020
FY2021	Fiscal Year Five: October 1, 2020 – September 30, 2021
FTO	Freedom To Operate
GE	Genetically Engineered
GM	Genetically modified
GOB	Government of Bangladesh
HICD	Human and Institutional Capacity Development
HYV	High Yielding Varieties
IAARD	Indonesia Agency for Agricultural Research and Development

IBC	Institutional Biosafety Committee
ICABIOGRAD	Indonesian Center for Agricultural Biotechnology Genetic Resources & Development
IEE	Initial Environmental Examination
IndoBic	Indonesian Biotechnology Information Centre
FAOSTAT	Food and Agriculture Organization Corporate Statistical Database
IP	Intellectual Property
IPM	Integrated Pest Management
IRB	Institutional Review Board
ISAAA	International Service for the Acquisition of Agri-Biotech Applications
IVEGRI	Indonesia Vegetable Research Institute
JRSC	J.R. Simplot Company
JTWG	Joint Technical Working Group
LBR	Late blight resistant (resistance)
M&E	Monitoring and Evaluation
MEL	Monitoring, Evaluating, Learning
MoEF	Ministry of Environment and Forests
MSU	Michigan State University
MTA	Material Transfer Agreement
NCB	National Committee on Biosafety
NCE	No Cost Extension: October 1, 2020 – September 30, 2021
NFT	Nutrient Film Technique
NGO	Non-governmental Organization
NTCCB	National Technical Committee on Crop Biotechnology
PERSUAP	Pesticide Evaluation Report and Safer Use Action Plan
PMT	Project Management Team
PPE	Personal Protection Equipment
R&D	Research and Development
SOP	Standard Operating Procedure
SNV	Single Nucleotide Variant
SSR	Simple Sequence Repeats
TAB	Technical Advisory Board
TLA	Targeted Locus Amplification
UMN	University of Minnesota

U of I	University of Idaho
USAID	United States Agency for International Development
USDA-FAS	United States Department of Agriculture – Foreign Agricultural Service



Indonesian potato field infected with late blight disease

TABLE OF CONTENTS

EXECUTIVE SUMMARY

PROJECT OVERVIEW AND STRUCTURE

PROJECT GOALS AND OBJECTIVES

PROJECT ACHIEVEMENTS BY OBJECTIVE

Objective 1

Objective 2

Objective 3

Objective 4

Objective 5

Objective 6

Objective 7

Objective 8

Objective 9

Objective 10

Objective 11

PROJECT MANAGEMENT

REGULATORY AFFAIRS

COVID-19 PANDEMIC IMPACT

ENVIRONMENTAL MANAGEMENT AND MITIGATION PLAN

OPEN DATA MANAGEMENT PLAN

FINANCIAL

FUTURE OF LBR POTATO

ANNEX I Project Personnel

ANNEX II Technical Advisory Board

ANNEX III	Project Formal Agreements
ANNEX IV	Project Partners and Collaborators
ANNEX V	HICD Knowledge Survey
ANNEX VI	HICD FY2017 Indonesia Workshop Overview
ANNEX VII	Core In-Country Technical Teams
ANNEX VIII	External Scientific Presentations
ANNEX IX	Scientific Publications
ANNEX X	Communications Strategy
ANNEX XI	Articles, Presentations, Videos
ANNEX XII	MEL Plan Overview
ANNEX XIII	Financial Documents



Bangladeshi potato farmer checks his potato crop

EXECUTIVE SUMMARY

The Feed the Future Biotechnology Potato Partnership, Cooperative Agreement Award number AID-OAA-A-15-00056, is a five-year, \$6.48 million multi-institution cooperative agreement between MSU, USAID, Simplot Company, and other global institutions to develop, introduce, and bring to market improved potato products in farmer- and consumer-preferred varieties in Asian countries. The project began USAID fiscal year (FY) 2016 and was set to conclude at the end of FY2020. However, the project was extended one year, through a no cost extension, and concluded activity on September 30, 2021.

The focus of the project was to introduce biotech potato products in Southeast Asia with broad-spectrum resistance to late blight (*Phytophthora infestans*), the most devastating potato disease in the world and highly endemic throughout the project's target countries of Bangladesh and Indonesia.

Why potatoes? Potatoes are the third most important food crop in the world following wheat and rice. Nutritionally they contain no fat, sodium, or cholesterol. One potato contains nearly half of the daily recommended value of vitamin C and is a good source of vitamin B6. Potatoes contain more potassium than a banana and are high in fiber, magnesium, and antioxidants. In addition, the potato produces more nutritious food, more quickly, on less land, and in harsher climates than any other major crop.

Late blight, the cause of Irish potato famine in the mid-1800's is one of the most serious diseases of potato. Late blight is caused by a water mold. Current methods of disease control are synthetic chemical fungicides. Farmers spray preventatively and numerous times throughout the cropping season as once late blight is detected it is almost impossible to control, often resulting in total crop loss. Therefore, farmers must spray to not risk losing their crop to late blight.

Bangladesh and Indonesia are both large potato producers who struggle with severe late blight disease. The crop is grown by thousands of smallholder farmers who can be greatly impacted by an LBR potato. Bangladesh is the seventh potato producing country in the world and ranks second after rice in terms of production in Bangladesh (FAOSTAT, 2020). The climate and environmental conditions in Bangladesh are susceptible to late blight disease. It has been reported that 30% of the total production cost is attributed to fungicides. In Indonesia, an ex-ante study done by the Agricultural Biotechnology Support Project II (ABSPII) project on the effects of a late blight resistant potato showed an increase in profits by 42.85% per hectare and a reduction in fungicide costs in the country between 50-80%.

Late blight resistant potatoes will offer Bangladesh and Indonesia smallholder farmers a resilient and sustainable solution to this devastating disease through reduced input costs and exposure to synthetic chemicals, improved food security by reducing post-harvest loss, and increased yields of a healthy, nutritious food source which can lead to reduced malnutrition and improved health. These net results are expected to improve the lives of the farmers, their families, and their communities.

Specifically, the Biotechnology Potato Partnership worked to build strategic human and institutional capacity building and support (research, development, and outreach) to in-country partners in Bangladesh and Indonesia to support access to, technology transfer, and sustainable use of biotech potato technologies. All activities supported and aligned with USAID's goal of increasing food security and resilience.

This final project report summarizes the achievements of the partnership in providing science-based answers and solutions to bring about food security, agricultural development, equality, and sustainability.

PROJECT OVERVIEW AND STRUCTURE

The Feed the Future Biotechnology Potato Partnership worked to introduce bio-engineered potato products in farmer- and consumer-preferred varieties into Bangladesh and Indonesia. These products, developed through gene insertion with stacked resistance genes, offer broad-spectrum durable resistance to late blight (*P. infestans*), the most devastating potato disease in the world.

The project built a collaborative partnership between USAID, Michigan State University (MSU), the University of Minnesota (UMN), the University of Idaho (U of I), the Bangladesh Agricultural Research Institute (BARI), the Indonesian Center for Agricultural Biotechnology Genetic Resources Research and Development (ICABIOGRAD), the Indonesia Vegetable Research Institute (IVEGRI), the International Potato Center (CIP), and the J.R. Simplot Company (JRSC). The project provided strategic human and institutional capacity building support (research, development, and outreach) to in-country partners to support access to, technology transfer, and sustainable use of biotech potato products.

The Biotechnology Potato Partnership was led by the Project Director supported by a Project Management Team (PMT). The PMT included experts in the following areas: Communications, Human and Institutional Capacity Development (HICD), Finance, Intellectual Properties (IP), Molecular Research, Monitoring and Evaluation (M&E), Pathology Research, Regulatory Affairs, and Socioeconomics. A dedicated Project Manager led the PMT and coordinated closely with the Project Director. Partner country activity was managed by project in-country coordinators. See Annex I for the complete list of project personnel.

A Technical Advisory Board (TAB), representing USAID and public and private sector groups globally provided strategic technical and specialist advice to the project. See Annex II for the complete list of TAB members.



Potato harvest in Bangladeshi

PROJECT GOALS AND OBJECTIVES

The Biotechnology Potato Partnership contributed to the goals of 1) reducing malnutrition and improving health; 2) reducing the use of harmful pesticides; 3) reducing pre-and post-harvest losses; 4) improving the social and economic standing of women; and 5) catalyzing economic growth.

Specifically, the project worked toward 11 objectives:

- Objective 1** Build a network of late blight related potato projects
- Objective 2** Bring the results of the ABSPII SP951 hybrid (Legacy Potato) to deregulation, dissemination, and commercialization
- Objective 3** In conjunction with the J.R. Simplot Company, develop, test, and deregulate a 3 R-gene LBR potato in Granola & Diamant varieties
- Objective 4** In conjunction with the International Potato Center (CIP) Kenya LBR potato project, test a 3 R-gene LBR potato containing the RB, vnt1, and blb2 resistance genes in the Desiree variety in Indonesia and Bangladesh
- Objective 5** Test the resilience of RNAi technology in the Katahdin variety at MSU
- Objective 6** Build the bio-safety capacity of partner institutions in Indonesia and Bangladesh
- Objective 7** Build the scientific capacity of partner institutions in Indonesia and Bangladesh
- Objective 8** Improve gender balance in partner institutions
- Objective 9** Demonstrate the socio-economic benefits of 3 R-gene LBR potatoes
- Objective 10** Advance the knowledge of the scientific community regarding GM LBR potatoes
- Objective 11** Effectively communicate project achievements and benefits of the GM potato to project personnel, stakeholders, and the public

The Biotechnology Potato Partnership used these strategic goals and objectives to develop annual operational goals that kept the project focused and accountable.

PROJECT ACHIEVEMENTS BY OBJECTIVE

Objective 1 – Build a Network of Late Blight Related Potato Projects

Description: The Biotechnology Potato Partnership involved a collaborative partnership between USAID, Michigan State University, the University of Minnesota, the University of Idaho, the Bangladesh Agricultural Research Institute (BARI), the Indonesian Center for Agricultural Biotechnology Genetic Resources Research and Development (ICABIOGRAD), the Indonesia Vegetable Research Institute (IVEGRI), the International Potato Center (CIP), and the J.R. Simplot Company (JRSC). The expanded this network and pursued strategic partnerships with other global institutions working directly or indirectly with late blight related potato projects.

Activities and Results: The project hit the ground running, quickly signing subawards with partners the University of Minnesota, the University of Idaho, and Simplot Plant Sciences. These relationships formed the core U.S.-based project team and provided a solid base of dedicated experts. As international partnerships were identified, the Biotechnology Potato Partnership worked to secure a memorandum of understanding (MOU) with the Bangladesh Agriculture Research Council (BARC), the Indonesia Agency for Agricultural

Research and Development (IAARD), and CIP, and letter of agreement (LOA) with partner BARI. This led to subawards with ICABIOGRAD and BARI. See Annex III for a listing of these formal agreements.

In addition, Article IV of the BARC MOU identified an additional advisory group of Bangladeshi stakeholders to provide guidance, review the project progress and activities and facilitate cooperation. The Joint Technical Working Group (JTWG) was comprised of the Executive Chairman of BARC, who served as the JTWG Chairman; the Biotechnology Potato Partnership Bangladesh Coordinator, served as committee member; the Director General of BARI, served as a committee member; Representative from the Ministry of Agriculture, served as a committee member; the Director of Crops, BARC, served as a member; and the principal investigator of the project, served as the committee secretary. The MOU was fully executed during FY2018. The JTWG was officially formed during the first half of FY2019 and met formally in Bangladesh.

During FY2017 the Biotechnology Potato Partnership also identified synergies that could be leveraged through a collaboration with the Feed the Future Southeast Asia Eggplant Improvement Partnership. This project, led by Cornell University, was also working with genetically engineered crop research in Bangladesh. The common genetically engineered research component of this project focused on eggplant (or brinjal as referred to in Bangladesh), provided a natural fit for collaboration between the two USAID projects. The projects then created the Bangladesh Biotechnology Partnership Joint Task Force (BBPJTF) to seek economies of scale, eliminate redundancies of activities, and collaborate on shared interests. The partnership shared physical office space in the Mohakhali DOHS neighborhood of Dhaka and personnel, including a country coordinator and communications coordinator.

The Biotechnology Potato Partnership's TAB (*Annex II*) was formed in FY2016. The group was comprised of experts across the biotechnology sector including, regulatory, research and development, NGOs, government organizations, and the private sector. This group met regularly with the project team and provided invaluable expert guidance and leadership.

The Biotechnology Potato Partnership continued to seek out and form partnerships and collaborations throughout the life of the project, collaborating overall with 20 organizations working in seven countries. The project placed a high value on and commitment to forge collaborations to build a diverse network. The addition of this global perspective and expertise allowed the project to leverage synergies and use funds strategically. The project engaged with global partners focused on biotechnology research, outreach and advocacy, stewardship, development, and education. See Annex IV for a complete list of formal and information project partners and collaborators.

Lessons Learned: Building a network of late blight potato projects required involving many more organizations and groups than those only focused on advancing late blight potato. Many of our collaborators had no direct focus regarding potato but rather mandates around biotechnology and genetically engineered products. The project learned early that a wide net needed to be cast well beyond late blight potato projects to ensure success and acceptance of the technology. This was especially true in biotechnology regulation and advocacy. Collaborations with biotechnology advocacy groups provided the project historical knowledge and support to help navigate complicated and changing partner country biosafety regulatory systems.

Biotechnology communication and advocacy groups also provided insights and expertise on how to manage anti-GMO activists and activity, especially in the first couple years of the project when much of the activity focused on the technical aspects of the project rather than establishing communications guidelines and protocol for dealing with anti-GMO groups rather than a trial-and-error approach.

The lessons learned in establishing these partnerships were that, although very important, it is a very time-consuming activity. In order for the partnerships to be meaningful, the project had to build trust and understand local bureaucracies.

Objective 2 – Bring the results of the ABSPII-funded Katahdin SP951 event (Legacy Potato) to deregulation, dissemination, and commercialization

Description: This objective was the result of an additional mandate to the project at the request of USAID.

In the approved proposal, the Biotechnology Potato Partnership committed to the following regarding the previous project, ABSPII funded by USAID on single gene LBR potato. The ABSPII project was led by Cornell University:

- Review of project data prior to finalizing the technical roadmap for developing multi-gene potato events for Asian farmers. The project was to review combination control mechanisms using the ABSPII single gene events and fungicides and consider these lines for use in durable resistance strategies using co-cultivation of mixed events containing different R genes to help ensure spatial and temporal diversity for long-term resistance.
- For the existing ABSPII LBR potato products, the Biotechnology Potato Project would seek regulatory approval if the products could be a part of an integrated pest management (IPM) system including fungicides and/or mixed population deployment to manage pest evolution in the field.

In addition to the above activities, the additional mandate requested by USAID, was to complete the process of deregulation of the selected event (SP 951 = Katahdin transformed with the RB gene) and the variety registration of the selected line (D951= Hybrid clone of SP 951 x Diamant) of the single R-gene late blight resistant potato (1G-LBR) developed under the ABSPII project).

Activities and Results: To avoid confusion with our 3 R-gene potato product, the Biotechnology Potato Partnership relabeled the work as the Legacy Potato. It was understood that at the start of ABSPII that the Katahdin SP951 event was the initial transformation event for gene discovery at UW-Madison. ABSPII sent SP951 to India, Indonesia, and Bangladesh to test, in their environment, as a “proof of concept”. ABSPII intended to develop new transgenic events in farmer preferred potato varieties. Unfortunately, the attempts made proved unsuccessful. Nearing the end of funding, ABSPII made a decision to attempt to move towards regulatory release of the SP951 event and molecular analysis was started, primarily in India and Indonesia. Bangladesh did not have the capacity for analysis, however, they were still interested in releasing the event in their country. The work of the ABSPII project in Bangladesh stalled in regulatory data analysis and dossier preparation. In Indonesia the project was more advanced, having submitted a regulatory dossier for event approval. However, after translation of the dossier from Indonesian Bahasa language to English, and further review of the data collected in both Indonesia and Bangladesh, it was evident that certain key pieces of information were missing, requiring further molecular analysis, field testing and data collection.

At the start of the project, our regulatory team worked together with USAID to obtain data and documents collected by ABSPII. We were expecting to be able to help release the SP951 event in both of our target countries, Indonesia and Bangladesh. This product could be used as a training tool for both countries, gaining experience on a GM release, while we work on developing our more sustainable 3-gene product.

The project had to face the following challenges in the deregulation and general release process of the ABSPII potato:

- According to the data obtained from India and Indonesia (and confirmed by scientists in both countries) the molecular characterization was not complete in several areas.
- The T-DNA was not fully sequenced. The RB gene was sequenced using cDNA, however, they were not able to sequence and have no data that shows the T-DNA was sequenced. A requirement needed to meet regulatory standards.
- Full backbone analysis was not completed. The only data submitted, showed that there was no PCR amplification of one gene located in the vector backbone. Other genes were not checked with

PCR and confirmation of no small fragments of backbone were reported on, both requirements were not completed.

- Flanking sequence analysis was attempted. The results were incomplete and inconclusive. Our regulatory team and advisors could not accept the data.
- Field trial data was not at the standards needed to meet regulatory standards and at least 1 field trial was still needed to be conducted in both countries.
- The regulatory dossiers that were submitted for both countries were completed and submitted by in country collaborators after ABSPII ended and before the project could review the data.

The project invested countless hours and efforts in trying to complete what was lacking in order to not only win regulatory approval in the two countries, but also to meet the standards of the international community. During FY2016 and FY2017 the MSU Molecular Lead completed molecular characterization of the event Katahdin SP951. This characterization, which was not conducted during the USAID-funded ABSPII project, was essential in determining the insertion site(s), insert integrity and insertion of plasmid used for the transformation of the event is required information in a regulatory dossier and used in the risk assessment by regulatory authorities to support the weight of evidence for no unintended effects on human health and the environment. The results obtained from the analysis done by a very experienced scientist at MSU on the SP951 event (MSU obtained this event directly from University of Wisconsin-Madison) proved to be very unique in deregulating an event.

- Analysis of the backbone was completed at MSU using PCR analysis and confirmed with genomic sequencing in the SP951 event. Unfortunately, 15,000bp of the 21,000bp backbone DNA was found in the plant. The Indian and Indonesian scientists tested the backbone region that contains the Tetracycline resistance gene and their results showed that the area was not present in the SP951 event. We also found that to be true, however, nearly all of the backbone downstream of that gene is present. This data has been confirmed and corroborated.
- Flanking sequence analysis. Now that we knew exactly what T-DNA and backbone were present, we were then able to find the ends and complete the flanking sequence analysis. This analysis revealed a unique situation. The insert went into SP951 in two segments. One segment (the Right Border and RB gene) is inserted on Chromosome 4. Another segment (the NPTII gene and the backbone DNA) is located on Chromosome 3. Confirmation PCR amplifications were done on all the junction sequences and sequences were confirmed along with an additional 1kb of flanking genomic sequence. A diagram of this is presented in Figure 1 below.
- From this data, unique PCR primer sets were also used to confirm that the SP951 event we received from UW-Madison correctly matched the events received in Indonesia and Bangladesh.
- Additionally, we completed a segregation analysis to add additional proof of our findings. We crossed the SP951 event and an MSU variety. According to the molecular analysis we expect:

25% of the progeny should have BOTH segments (RB and NPTII/Backbone)

25% of the progeny should have only the RB segment

25% of the progeny should have only the NPTII/Backbone

25% of the progeny should have neither

Our results exactly matched our expected results, further confirming the two segments had inserted separately.

As part of ABSPII, both groups in Indonesia and Bangladesh used the SP951 event in crosses with varieties used in their countries. At MSU, we tested the progeny by having the countries send DNA samples. The project found that in Bangladesh they only kept one (D951= Hybrid clone of SP 951 x Diamant) and this tested to have both the RB and the NPTII/backbone segments. In Indonesia, they kept five progeny and three of them had only the RB segment. These three do not have the NPTII/backbone segment.

It is understandable, but nonetheless unfortunate, that the ABSPII team was not able to complete the molecular analysis on the SP951 early on. With this segregation, RB resistant plants without NPTII could have been released. We understand that the focus was creating new events and it was only in the end that SP951 was considered as a product.

The Biotechnology Potato Project and USAID agreed that it was no longer practical to seek deregulation of SP951 in Bangladesh. In Indonesia, ICABIOGRAD has an RB only progeny and they did decide to continue with the progeny as a releasable event.

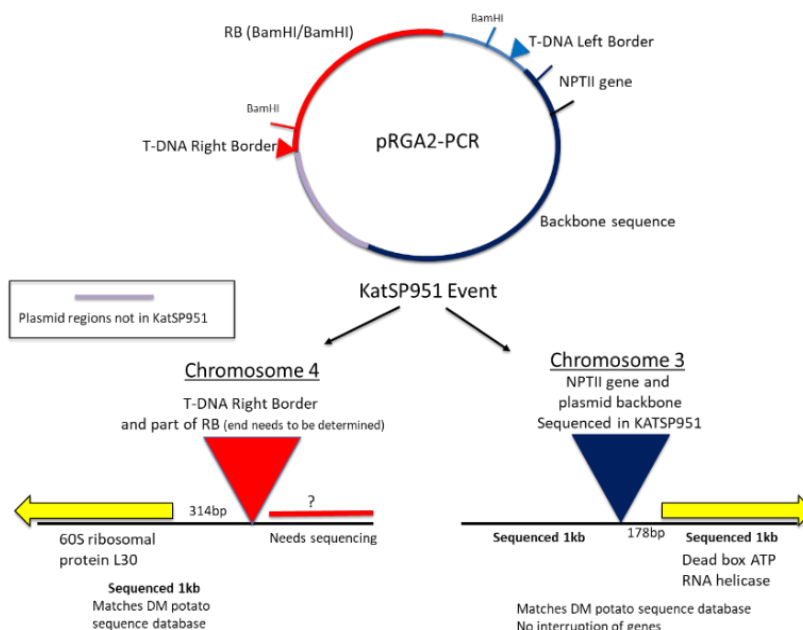


Figure 1. Location of the RB gene, vector backbone, and NPTII marker gene in Katahdin SP 951. The RB gene was found in chromosome 4 and the vector backbone along with the NPTII marker gene was found in chromosome 3.

The findings that some vector backbone had been transferred to the plant during the transformation is not unusual. However, the large amount of vector backbone in the Legacy potato and the splitting of the inserted DNA onto two separate chromosomes are unusual for deregulation of an event. Additionally, the fragmentation, in this case, left both the RB gene and the NPTII gene intact and functioning but inserted separately was also a surprising result. A decision to approve this potato variety with the presence of the vector backbone would likely be open to scrutiny by the international regulatory community. There is little precedent for assessing the risk of a large amount of vector backbone including bacterial genes in any approved GM crop. It was determined by the MSU team that the further assessment of this risk would require additional lengthy and costly experimentation to show that the bacterial genes are not expressed. If the bacterial genes are expressed, a complete risk assessment of these genes would be necessary. The presence of bacterial genes in the backbone will also raise concerns over horizontal gene transfer, which also is difficult to assess.

Overall, all findings on Legacy Potato supported the recommendation by the Biotechnology Potato Partnership to discontinue commercialization efforts of the Katahdin SP951 event in Bangladesh. These findings and recommendations were shared with USAID and the BARI Director General for advisement.

During FY2018 after a careful review by the Project Management Team, consultation with the TAB, and discussion with in-country partners, the decision was made to end all deregulation and commercialization support for Legacy Potato. This decision was made in part due to the prior year molecular findings in with the Bangladesh products as detailed above. In addition, CFT's in Indonesia did show that their Legacy single gene LBR potato events did offer some resistance to late blight, but still required significant intervention with chemical fungicides to protect against the disease. The decision to suspend work on the Legacy Potato was supported by USAID and all work on it officially concluded in FY2018.

Bangladesh concluded their independent research with the Legacy Potato in FY2021 while Indonesia continued to move the single gene potato through the Indonesian regulatory system, receiving food safety and environmental safety approvals from their regulatory authorities, and in FY2021 applied for varietal release. The Indonesian application for varietal release is pending approval.

The project produced two publications under this objective.

["Molecular Characterization for Risk Assessment of a GM Late Blight Resistant Potato: An Unusual Case,"](#) describing the DNA insert in the Legacy potato, was published in Transgenic Research in 2021.

"Experience in Developing Genetically Engineered Potato Resistant to Late Blight Disease" appears as a book chapter in [Genetically Modified Crops in Asia-Pacific from Research to Commercialization](#) published by Commonwealth Scientific and Industrial Research Organization (CSIRO) 2020.

Lessons Learned: The Biotechnology Potato Partnership committed to activities based on assumptions of a previous project work without first receiving and reviewing the research data. This negatively impacted the budget and allocation of resources (manpower, materials, etc.). Through an adaptive management approach, the project was able to adjust strategy and remain on task. In addition, the Legacy Potato and activities associated with it served as a valuable learning tool for the project research and regulation teams and was used as a case study to build regulatory capacity.

Objective 3 – In conjunction with the J.R. Simplot Company, develop, test, and deregulate a 3R-gene LBR potato in the Granola and Diamant varieties

Description: The Biotechnology Potato Partnership with Simplot Plant Sciences, developed, evaluated, and selected the top events using a multi-gene construct with three different LBR genes in Diamant and Granola varieties that provide superior and durable resistance to late blight. The three genes in the construct (*mcq1*, *vnt1*, and *blb1*) are R genes from *Solanum* species related to the domesticated potato. This construct also uses the NPTII gene as an antibiotic resistance marker, which is widely used and has global acceptance for genetically modified crops.

The JR Simplot Company is a family-owned and privately held international food and agriculture company with over 13,000 employees worldwide based in Boise, Idaho. Combining their extensive experience in agriculture with the latest in biotechnology, the Simplot Plant Sciences team developed Innate® Technology, an innovative biotechnology platform for improving crops. As a pioneer in the potato industry, Simplot has commercialized and is marketing GM potatoes in the U.S. (since 2014) and Canada (since 2016) with stacked genes which offer several traits including reduced black spot, lowered asparagine levels and reduced sugars. The company has extensive experience in biotechnology and offers the Biotechnology Potato Partnership state of the art, world-class research facilities and technologies.

Activities and Results:

Development of 3R-gene events

Through the partnership agreement with Simplot, the project agreed that the Simplot team would transform events in two farmer-preferred varieties, one for Bangladesh and one for Indonesia using a three-gene stack of late blight resistant genes identified from wild potato varieties that are designed to provide durable resistance to late blight disease. Simplot is providing these events to the project with rights for MSU to distribute to our research collaborators in Indonesia and Bangladesh. If the events are selected for commercialization MSU will develop the appropriate license or intellectual property agreement(s) with the approval of Simplot and PBL and executed with the governing bodies of ICABIOGRAD and BARI.

During FY2016 the project team identified and selected a farmer preferred variety for each focus country. The varieties were chosen after careful consideration and research into what farmers prefer and what varieties were accessible and suitable for transformation.

Potatoes are grown in Bangladesh in the winter. Diamant is a yellow smooth skin potato with oval to oblong tubers from the Netherlands. Potato production in Bangladesh has increased over the last few decades primarily due to the introduction of high yielding varieties (HYV), such as Diamant. The potato is the best land use to feed people compared to other staples in Bangladesh. The Diamant variety was selected as the target variety in Bangladesh.

In Indonesia, the Granola variety of potatoes is very popular. It is a fresh consumption table potato which is medium to large in size with a round to oval shape. The variety is also susceptible to late blight disease which is very prevalent throughout Indonesia and can appear days after emergence. For these reasons the project selected Granola as the target variety in Indonesia.



Diamant 3R-gene potato



Granola 3R-gene potato

Once the varieties were identified, Simplot began transformation with the 3 R-gene LBR construct (pSIM4392) which includes the NPTII antibiotic resistance gene as a selectable marker.

Simplot plant scientists, during FY2017, focused on the molecular screening and transformations of potato lines with 3 R-genes. They screened Granola 3-R gene events (n = 113) for molecular suitability (a single, complete insert with functional gene expression) and to identify the most highly resistant lines to advance to field testing in 2018. Less vigor (less foliage plant growth and poorly developing roots) was observed for the Granola transformants after standard greenhouse testing. This was further observed for the original Granola line grown at MSU which was obtained from the United States Potato Genebank. With long term tissue culture, some varieties experience loss of plant vigor and yield.

Due to the decreased vigor in the Granola transformants, the project team along with USAID decided to approve retransformations of a new line of the Granola variety obtained from the University of Idaho. Simplot completed the transformations in FY2018. The result was successful with better plant vigor in the transformed events.

The 3R-gene transformations of Granola and Diamant were further tested by Simplot. These tests included pathology testing with five (5) *P. infestans* strains. These strains are some of the most aggressive isolates that have been found of *P. infestans*. The results of these tests provide insight into how strongly each of the 3R-genes are expressing. The unmodified Diamant and Granola were highly susceptible.

From hundreds of transformed events, Simplot identified more than 10 events of each variety that were optimally expressing each R gene and determined to have only one complete T-DNA insert. The ten (10) highest performing events for both Diamant and Granola were transferred to MSU in FY2019. MSU continued technical research workplan activities which included propagation for the MSU tissue culture bank and nutrient film technology (NFT) seed production. NFT tuber production provided tubers for CFT's in Michigan, and Indonesia during FY2020 of the project. Plants of both varieties were grown in the greenhouse at MSU for phenotypic observation and tuber production. The Diamant events were received six months earlier than the Granola events and MSU was able to propagate and transplant to the field at MSU for agronomic evaluation and established on campus nursery for late blight disease resistance testing.

Confined Field Trials and Advanced Selection of Events

A significant accomplishment by the MSU team during FY2020 was the selection of two events out of the ten Diamant 3R-gene events received from Simplot. These two events were selected based on a review of field and greenhouse trial data and molecular assessment. The team examined characteristics such as plant growth, canopy growth, tuber type from trial data.

The Diamant 3 R-gene LBR CFT, planted in Indonesia, in March 2020 (photo at right), tested the two Bangladesh farmer-preferred variety Diamant 3 R-gene lines, non-transgenic Diamant and varieties Granola, Katahdin, Atlantic, and two single R-gene LBR lines against late blight disease. The CFT looked at both sprayed with fungicides and non-sprayed plots. The result found no late blight infection of the 3 R-gene LBR lines from the first observation conducted at 28 days after planting (DAP) to harvest 94 DAP. Other diseases such as bacterial wilt, suspected potato virus Y and early blight were found on these two lines.



Other data collected included: tuber yield per plot, tuber yield ton/ha, tuber yield per plant, average tuber number and tuber yield losses by late blight. In both sprayed and unsprayed plot, the two Diamant 3 R-gene LBR lines showed the highest yields per category and the lowest tuber yield lost due to late blight. The results of this trial in Indonesia are significant for progress in Bangladesh since the events have not yet been imported for trial in Bangladesh.

Also, due to delays in regulatory approvals in Bangladesh, along with the high prevalence of late blight in Indonesia, the project felt it important to send the two Diamant events to Indonesia for further field testing. The Indonesian CFT's provided excellent data for the Bangladesh-bound Diamant.



Indonesian project team visits CFT of 3R-gene LBR potato.

Despite the onset of the COVID-19 pandemic in third quarter of FY2020, the project complied with COVID-19 restrictions and found effective ways to conduct work and move research activities forward while staying safe and following all project and local government mandates.

The Granola 3 R-gene LBR CFT was planted at IVEGRI on July 21, 2020. This CFT tested six Indonesia farmer-preferred variety Granola 3 R-gene LBR events and non-transgenic variety Granola against late blight disease. The population of each plot was 30 plants with four replications. This CFT did not compare sprayed vs non-sprayed plots. It was a cultivar vs late blight susceptibility study and none of the plots were sprayed with fungicides. All plots were treated with insecticides to control insect pests. Observation of late blight was based on a rating system used to estimate the severity of potato late blight while observation on the bacterial wilt and viruses was based on the incidence of the disease. The first observation was made at 14 DAP and continued until before harvest when plants were sprayed with herbicide to stop plant growth.

Plant observations were made on the number of plants growing, starting at 21 DAP. Plant vigor was observed starting at 28 DAP. Observation of late blight and other pests and diseases started at 21 DAP. The U.S. Technical Team at MSU conducted two CFT's. An agronomy field trial with both the 3 R-gene LBR Diamant and Granola events was planted from NFT certified seed mini tubers at the MSU Montcalm Research Center. A CFT late blight trial was also planted at MSU which evaluated 3 R-gene LBR Diamant and Granola events planted from tissue culture plants.

In the Michigan State University 2021 agronomic trials two comparisons were made. The yield, specific gravity and tuber quality were compared between 1) the non-GM cultivated potato variety Diamant and three (3) 3-R gene Diamant events planted from NFT minitubers, and 2) the non-GM cultivated potato variety, Granola, and six (6) 3-R gene Granola events transplanted from tissue culture. These events demonstrated promising levels of resistance to late blight in initial laboratory screening conducted by Simplot. These lines also tested well in the October 2020 MSU Agronomy Trial.

The field variety trials were conducted at the Montcalm Research Center (MRC) in Entrican, MI. A randomized complete block design was used with three replicates (plots) per line. The plots were 23 feet (7 m) long and spacing between plants was 10 inches (25.4 cm). NFT tubers were used for planting. Inter-row

spacing was 34 inches (86.4 cm). Supplemental irrigation was applied as needed. Nutrient, weed, disease and insect management were based on commendations used by the commercial operations in Montcalm County. The field experiments were conducted on a sandy loam soil that is on a five-year rotation. Oats were grown in 2019 on this ground.

Data was collected on the total weight in kg of all tubers harvested per plot and the weight of all tubers graded as US#1 (marketable yield). US#1 includes all A size and oversized tubers that are firm and well shaped. Tubers were graded as A size: 2-3.25 in.; B size: < 2 in.; OV: Oversized: > 3.25 in.; PO: pickouts due to external defects and shapes. The % weight in each class was calculated out of the total weight. Specific Gravity (SPGR) was calculated from dry weight and submerged water weight of 10 US#1 tubers per plot. Specific gravity = (weight in air) divided by [(weight in air) - (weight in water)]. Cut tubers of US#1 were evaluated for internal defects including Hollow Heart (HH), Vascular Discoloration (VD), Internal Brown Spot (IBS), Brown Center (BC). The % tubers out of 10 with each defect was calculated for each plot.

Data on total weight, US#1 weight, and specific gravity were analyzed using one-way analysis of variance (ANOVA). Means comparisons were performed using Tukey's HSD.

Results

Some rain events stressed the crop but in general, the trial went well. The canopy of the events did not vary between the events. The events for both Granola and Diamant were similar to the non-transgenic controls. Using NFT mini tubers, some rain events and lack of adaptation to Michigan lead to some poor tuber shapes. The total yield and US#1 - marketable yield were not significantly different between non-GM Diamant and three of the 3-R gene Diamant events tested (MSU-DIA-UB014, -UB015, -UB255) (*Table 1*). Specific gravity, a measure of dry matter tuber content, was not significantly different between the GM events and the non-GM Diamant. Internal defects, a measure of tuber quality, were similar in the GM events and the non-GM Diamant, although this data was not analyzed statistically. In the Granolas we saw some bottleneck shaped potatoes and in the Diamant's we saw points. The GM Granola event GRA-MSU-UG239 had only one replication. The event GRA-MSU-UG277 had a lower yield than non-GM Granola. Among the other GM events, the total yield and marketable yield were not significantly different between them and the Granola non-GM (*Table 2*). Three of the GM Granola events (GRA-MSU-UG234, GRA-MSU-UG247 and GRA-MSU-UG265) had no significant differences in yield and quality than the non-GM Granola. These events also appeared the best phenotypically with the non-GM Granola. GRA-MSU-UG269 had a longer tuber shape. Marketable yield in this trial was likely impacted by the short growing window and the quality of the plot. A low spot was observed in the field making those plots more susceptible to flooding and disease. See harvest images below.

Conclusion

Ideal lead events to advance in the development of the GM LBR potatoes will, from a regulatory perspective, be the same as the non-GM variety used for the transformation in all characteristics other than an expected high level of resistance to late blight disease due to the introduction of the 3 R-genes, although a GM event with characteristics superior to the non-GM comparator might also be considered. The results from this Diamant trial suggest that the 3 R-gene Diamant events DIA-MSU-UB014, DIA-MSU-UB015 and DIA-MSU-UB255 are suitable candidates to advance for the project, based on comparable yield and specific gravity with the non-GM Diamant. The results from the Granola trial suggest that GRA-MSU-UG234, GRA-MSU-UG265 and GRA-MSU-UG269 are the most similar to the non-GM Granola in phenotypic characteristics, yield and specific gravity. The results from these trials will be considered along with evaluation of the molecular characteristics and evaluation in the fields in the target countries to select the lead events.

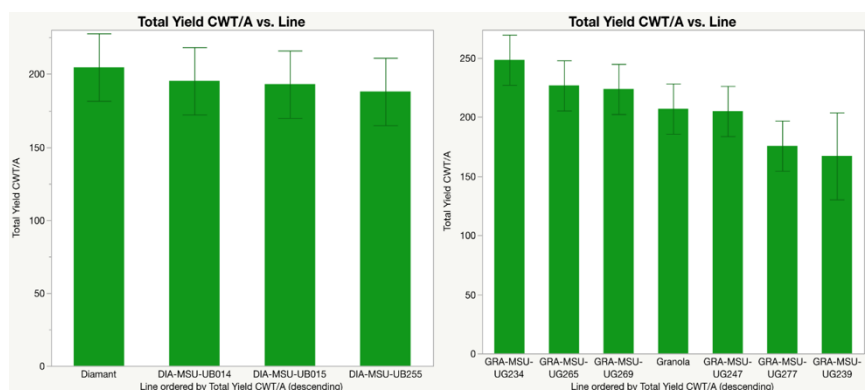


Table 1. Results from 2021 Diamant trial at Montcalm Research Center, Entrican MI, U.S.: Planted 5/8/21, Harvested 10/1/21. See methods for descriptions of abbreviations.

Line	Weight (cwt/a)		Percent by Weight					Quality (%)			
	TOTAL	US#1	Bs	As	OV	PO	SPGR	HH	VD	IBS	BC
DIAMANT	195a	82	57	40	0	1	1.081a	0	0	63	0
DIA-MSU-UB014	193a	77	61	39	0	3	1.081a	6	3	23	0
DIA-MSU-UB015	188a	64	65	33	0	2	1.082a	0	0	33	0
DIA-MSU-UB255	205a	65	64	34	0	3	1.080a	0	3	43	0

*Means followed by same letter do not significantly differ (P=.05, Tukey's HSD).

Table 2. Results 2021 Granola trial at Montcalm Research Center, Entrican MI, U.S.: Planted 5/8/21, Harvested 10/1/21. See methods for descriptions of abbreviations.

Line	Weight (cwt/a)		Percent by Weight					Quality (%)			
	TOTAL	US#1	Bs	As	OV	PO	SPGR	HH	VD	IBS	BC
GRANOLA	207ab	57	59	27	0	14	1.061	0	0	0	0
GRA-MSU-UG234	248a	78	58	31	0	11	1.060	0	6	3	0
GRA-MSU-UG239**	167b	46	66	28	0	6	1.066	0	20	0	0
GRA-MSU-UG247	205ab	88	45	42	0	12	1.071	0	10	20	0
GRA-MSU-UG265	227a	75	49	34	0	17	1.065	0	6	0	0
GRA-MSU-UG269	224a	82	44	36	0	20	1.067	0	16	0	0
GRA-MSU-UG277	176b	47	54	26	0	19	1.066	0	6	0	0

Means followed by same letter do not significantly differ (P=.05, Tukey's HSD). **UG239 only had one replication

Harvest Images:



Diamant NonGM



DIA-MSU-UB014



DIA-MSU-UB015



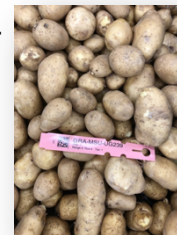
DIA-MSU-UB255



Granola NonGM



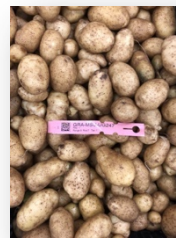
GRA-MSU-UG234



GRA-MSU-UG239



GRA-MSU-UG265



GRA-MSU-UG247



GRA-MSU-UG277



GRA-MSU-UG269

Importation and Contained Trial in Bangladesh

During FY2020 the project reached another milestone with the import of the two selected 3 R-gene LBR Diamant events into Bangladesh. Although the project hoped that the Bangladesh regulatory authorities would approve a CFT without first planting a greenhouse trial, the project was required to fulfill the greenhouse trial requirement prior to applying for a CFT permit. The greenhouse trial showed favorable results and the project at the end of the NCE was awaiting approval for the first CFT.

Study Title: FTFBPP DIA-MSU-UB015 and DIA-MSU-UB255 Contained Trial

Study Dates: Start Date: April 12, 2021 (Planting) Termination Date: Aug 11, 2021 (Harvest)

Principal Investigator: Dr. Yousuf Akhond, Bangladesh Principal Investigator, BARI

1. Purpose

This contained trial was conducted to compare the response of two GM (genetically modified) potato events to the late blight pathogen in Bangladesh using detached leaf bioassays and to compare other phenotypic characteristics. The two GM potato events, DIA-MSU-UB015 and DIA-MSU-UB255 were compared to the non-GM potato variety Diamant from greenhouse grown material and to propagate additional seed potato for a future field trial. The comparison provides an indication of the efficacy of the GM plants against the late blight pathogen and serves as an initial evaluation of intended and unintended differences relevant for food safety and environmental risk assessments.

2. Regulatory Compliance

This contained study includes GM and non-GM potato lines that were imported from Michigan State University in the US. Regulatory requirements as described in the Biosafety Guidelines of Bangladesh, Ministry of Environment and Forest (2005), and in the permit application and terms and conditions of the permit approval, and the phytosanitary import permit were strictly followed. All procedures, including the Study Plan and any Standard Operating Procedures relating to confinement of the regulated plant material were read, understood, and followed by the project personnel.

Permission to import and conduct a contained trial had been granted by the Bangladesh regulatory authorities, and an import permit had been granted by the plant quarantine office for all material shipped from MSU for this trial.

3. Study Design

3.1 Starting Plants

Mini-tubers of DIA-MSU-UB015, DIA-MSU-UB255, and non-GM Diamant provided by Dr. David Douches, Michigan State University were shipped to BARI via DHL according to all relevant import and phytosanitary requirements. The mini-tubers were received at BARI on January 20, 2021 (photo at right) and placed in storage until planting.

The plants were grown in one room of the greenhouses of the BARI Biotech Division. The greenhouse where the plants were grown was locked and a sign that stated 'GM Material – For Research Purposes Only', or similar language, was posted at the greenhouse entries. Pots in the greenhouse were labelled with tape on the side of each pot with the name of the potato line.



3.3 Description of Experimental Design

Trial Design. Eighty (80) mini-tubers were planted in 80 pots per line, with one mini-tuber planted in each pot. A total of 80 plants per line x 3 lines = 240 plants (pots) total in the study. Pot size: Diameter: 9-inch; Height: 8 inch; Spacing: 45cm x 36cm (between row to row and pot to pot).



Planting. Mini-tubers were planted in the greenhouse on April 12, 2021 (photo at left). Details of planting and disposal or storage were recorded on the appropriate form, according to SOP3 for Identification and Inventory.

Trial Termination. At the end of the contained trial and the seed multiplication, all tubers produced in the pots were harvested and stored under appropriate conditions and in compliance with SOP3 for Identification and Inventory until planting in the field in the fall of 2021. All other potato plant material from the trial was destroyed by burning and burying in disposal pit in the confined field in front of the biosafety officer. Soil from the pots were disposed of in a pit and covered with topsoil and was not reused.

4. Data Collection

4.1 Observations

The resistance of the two GM events and non-GM variety Diamant to late blight was compared in detached leaf bioassays described below. A comparison of phenotypic/agronomic characteristics described below was also carried out.

Phenotypic/agronomic Comparison

For each of the three lines, the following measurements were made for each of 12 pots as replicates:

1. Days to plant emergence
2. Plant height (cm), no. of leaves, no of stems at 3 weeks
3. Plant height (cm), no. of leaves, no of stems at 6 weeks
4. Plant height (cm), no. of leaves, no of stems at 9 weeks
5. Total number of tubers at harvest
6. Total weight (g) of tuber per plant or pot at harvest
7. No. and weight of tubers graded by weight (g)

Grades: i) 5-10 g; ii) 10-20 g; iii) 20-30 g; iv) >30 g

Detached Leaf Bioassays

4.2 Samples

Leaf material was collected during the contained trial for Detached Leaf Bioassays (DLBs). No viable plant material (tubers, seeds, etc.) were collected for DLBs during the contained trial period. Tubers were harvested at the end of the trial as described in Section 3.3.

Leaf samples were collected from four of the plants from each event for DNA extraction and PCR analysis. Unique primer sequences, provided by MSU, were used for a PCR analysis to test the identity of the two GM events. DNA extracted from leaf tissue collected of the non-GM Diamant in the greenhouse trial was also used as a control for the PCR analysis.

4.3 Statistical Analysis

Means were based on 12 replicates per line (12 pots/1 plant per plot). Data was analyzed using one way analysis of variance (ANOVA). Means comparisons were performed using Tukey's HSD.

5. Results

No significant differences were detected between the GM events and the non-GM Diamant for the phenotypic characteristics measured, with the exception of number of leaves per plant at three weeks. Number of leaves per plant was higher in DIA-MSU-UB015 than the other two lines at three weeks, but not significantly different at six or nine weeks. (*See Table 3*)

There were no significant differences between the GM events compared to the non-GM Diamant in yield measured as the number of tubers. Some differences were detected in weight and tuber size at harvest. DIA-MSU-UB015 produced significantly more tubers by weight than the non-GM Diamant. The total weight of tubers produced by DIA-MSU-UB255 was also higher than non-GM Diamant, but the measurements across the 12 plants (pots) was too uniform to conduct the analysis of variance, so the statistical significance for this line compared to the others could not be determined. (*See Table 4*)

Table 3. Results of the phenotypic comparison between the two 3 R-gene Diamant events and the nonGM Diamant. (Measurements described in section 4.)

Lines	Days to Emergence	3 Weeks			6 Weeks			9 Weeks			No. of Tubers	Weight of Tubers (g)
		Plant Height (cm)	No. of Leaves	No. of Stems	Plant Height (cm)	No. of Leaves	No. of Stems	Plant Height (cm)	No. of Leaves	No. of Stems		
DIA-MSU-UB015*	8 -	27.8 -	12.3 a	1.8 -	62.6 -	20.4 -	3.9 -	89.7 -	26.9 -	5.2 -	7.3 -	185.0 a
DIA-MSU-UB255*	8.4 -	26.5 -	10.8 b	1.7 -	59.7 -	18.4 -	2.8 -	87.3 -	23.6 -	4.7 -	9.2 -	174.4
Non-GM Diamant*	7.7 -	28 -	10.5 b	2.3 -	62.7 -	18.8 -	3.4 -	93.3 -	24.3 -	6.5 -	8.1 -	167.8 b

* Means followed by same letter or symbol do not significantly differ (P=.05, Tukey's HSD).

Table 4. Results of the yield (weight in grams, tuber count) comparison between the two 3 R-gene Diamant events and the non-GM Diamant. (Measurements described in section 4.)

Line	Tuber Weight (g)						Tuber Count					
	<5g	5-10g	11-20g	21-30g	>30g	Total	<5g	5-10g	11-20g	21-30g	>30g	Total
DIA-MSU-UB015*	3.4 b	5.2 -	20 -	18 -	134 a	185 a	1.8 b	0.8 -	1.6 -	0.5 -	1.8 -	7.3 -
DIA-MSU-UB255*	7.7 a	5.3 -	18 -	19 -	121	174.4	3.8 a	0.9 -	1.2 -	0.8 -	1.9 -	9.2 -
Non-GM Diamant*	4.1 ab	6.4 -	27 -	17 -	108 b	167.8 b	2.1 ab	1 -	1.8 -	0.7 -	2 -	8.1 -

* Means followed by same letter or symbol do not significantly differ (P=.05, Tukey's HSD). Means followed by no number or symbol were too uniform across replications to conduct an ANOVA.

The results of the detached leaf bioassays showed the percentage of diseased leaf area was significantly higher in the non-GM Diamant compared to the two GM events at four, seven, and 10 days after infection in all three repetitions of the experiment, except for day four in experiment two. No infection at all was observed on any of the infected leaves from GM plants. Infection was not observed until day seven in experiment two. The relative area under the disease pressure curve (RAUDPC) was calculated from the four, seven, and 10 day ratings to give a measure of the rate of infection progress in the inoculated leaves. The disease progressed at significant rate in the non-GM Diamant compared to the GM events where zero disease was observed over the 10 day period of the experiments.

PCR analysis was completed to check the identity of the two GM events. The expected unique band was present in each of the two events (four reps) compared to the absence of the band in the non-GM Diamant using the same primers unique to each event. (A water sample (no DNA) was also used as a control to demonstrate no contamination).

6. Conclusion

The results of the contained trial were as expected. The two late blight resistant GM potato events, DIA-MSU-UB015 and DIA-MSU-UB255, which are the Bangladesh farmer-preferred variety Diamant transformed with 3 R-genes, showed total resistance to the late blight pathogen compared to the non-GM Diamant where 100% of leaf area was infected after 10 days in two out of the three DLB experiments. Also, as expected, other characteristics of the two GM events measured in the greenhouse grown plants, including plant emergence, plant height, leaf number, stem number, tuber number and tuber weight, did not differ significantly compared to the non-GM Diamant. These results indicate that there are no unanticipated differences between the GM and the non-GM Diamant. Although a significant difference in yield was detected, differences from greenhouse grown plants may be anomalous; results from a field trial are necessary to draw any conclusion.

The intended modification is late blight resistance, and the GM Diamant events show total resistance compared to the non-GM Diamant in DLBs using virulent Bangladesh isolates of the late blight pathogen for inoculation. The critical next step is to test these GM events under field conditions in a confined field trial in Bangladesh to confirm the results from the contained trial.

At the close of the FY2021 the project technical team is also narrowing in on the selecting the two Granola 3R-gene LBR events for continued testing and commercialization. The team is following the same protocols used to select the two Diamant events. During FY2020, the MSU technical team advanced molecular analysis of these events. After advanced molecular analysis three events have been selected to advance to regulatory characterization and commercial release: MSUDIA_UB255, MSUDIA_UB15, and MSUGRA_UG269. Two additional events, MSUGRA_UG234 and MSUGRA_UG265 events have also been selected for further molecular analysis.

The advanced molecular analysis included:

1. Determination of the insertion site of the inserted T-DNA,
2. Characterization of the insertion for deletions and extra inserted DNA,
3. Sequencing of the junction between insert and chromosome,
4. Sequencing the 1kb of flanking chromosomal DNA on the left and right border,
5. Matching the flanking chromosomal DNA to the MSU DM Database and confirmation that the insert does not interrupt any genes,
6. Analysis of the left and right junction regions for newly created open reading frames.



Biotechnology Potato Partnership Pathologist at BARI conducting detached leaf bioassays in 3R-gene Diamant greenhouse plants

Pathology Research

The Biotechnology Potato Partnership realized the importance of understanding and mapping *P. infestans* across the target countries of Bangladesh and Indonesia. As a part of Objective #3, the project implemented an aggressive workplan for the survey and collection of pathogens for each country.

During FY2016, the project obtained permits for bringing *P. infestans* isolates from Indonesia and Bangladesh into the U.S. In addition, MSU obtained DNA of *P. infestans* isolates from Bangladesh which were characterized guided by the Euroblight database and with pro-bono support from Dr. David Cooke of the James Hutton Institute in the UK. Also, an Indonesian project team led by a plant mycologist from IVEGRI, surveyed *P. infestans* incidence in West Java and collected isolates of *P. infestans* from major growing areas of potato such as Pangalengan (Bandung), Lembang (West Bandung), Garut, and Majalengka. The host plant, location, elevation, time, and diseased severity were collected. Three isolates were collected per location for a total of 12 isolates.

During FY2017, the pathologist at BARI was selected for the project and staff in both Indonesia and Bangladesh underwent training in techniques required to isolate *P. infestans* from infected tissue and to get and maintain pure cultures which could be used for further phenological and genotype characterization.

In FY2018 and FY2019, the project continued monitoring of pathogen, *P. infestans* in Bangladesh and Indonesia. Initial characterization and genetic analyses of *P. infestans* populations in Bangladesh and Indonesia were completed from FTA cards and five live isolates from cultures. In Indonesia, this analysis was completed in FY 2019.

This work included genotyping using simple sequence repeats (SSRs), mating type, metalaxyl sensitivity testing and mitochondrial haplotype testing. In Bangladesh, results show that all living isolates from the Gazipur area were mating type A2, indicating no chance of sexual recombination of *P. infestans* isolates in this area. These isolates were also found to be insensitive to metalaxyl, one of the most commonly used late blight fungicides. This finding suggests that the use of metalaxyl-based fungicides in Bangladesh should be discouraged, as they would be ineffective in controlling late blight.

Through the project's publications, these results were shared with the scientific community, extension groups and potentially other international development groups to help promote and encourage fungicide resistance management strategies such as rotation of fungicide chemistries and tank mixing systemic fungicides with protectant fungicides. The use of metalaxyl-containing fungicides should also be discouraged since they are ineffective in controlling the strains of the late blight pathogen that are present in Bangladesh.

Genotyping of Bangladeshi isolates from the five divisions in Bangladesh showed that they were all closely related to the European genotypes. In Bangladesh, a comprehensive survey of the potato growing regions was carried out and *P. infestans* isolates were collected from infected potato and tomato plants. The results of the genotyping and population studies showed that 90% of the isolates from potato were the European genotype EU_13_A2. The other 10% were unique to Bangladesh but more closely related to the European genotypes than the genotypes found in North America. Most of the isolates of *P. infestans* collected from tomato were more closely related to the European genotypes EU_6_A1 and EU_1_A1 and only three grouped together with EU-13_A2 isolates from potato (Figure 2). Furthermore, discriminant analysis of principal components showed that all the isolates from tomato segregated separately from those on potato (Figure 3).

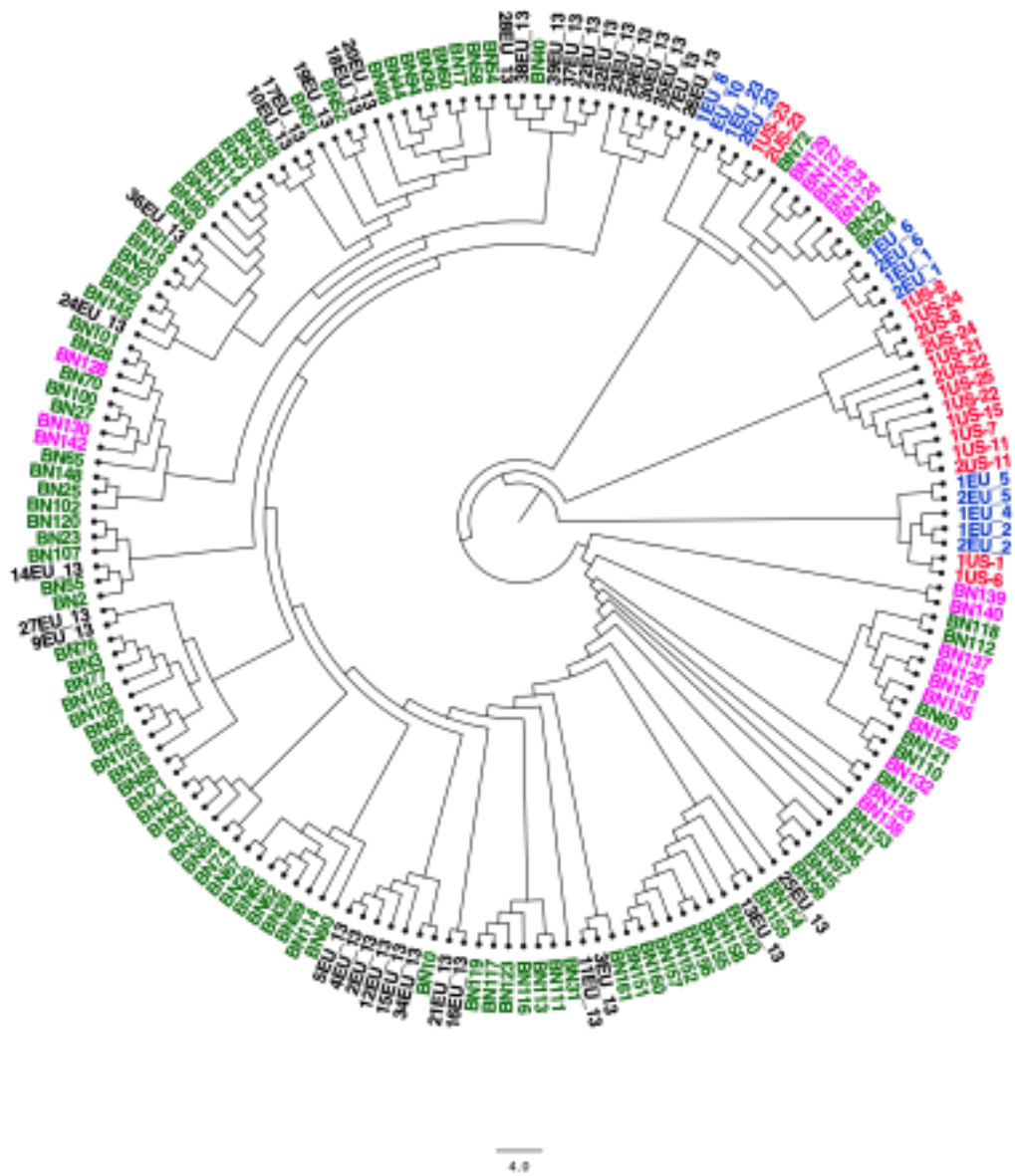


Figure 2. Neighbour joining tree based on Bruvo's genetic distance for *Phytophthora infestans* populations from five divisions of Bangladesh with 1,000 bootstraps replicates. (Node labels: black = standard EU_13_A2 genotypes, green = Bangladesh samples from potato, pink = Bangladesh samples from tomato, red = US genotypes and blue = other European genotypes).

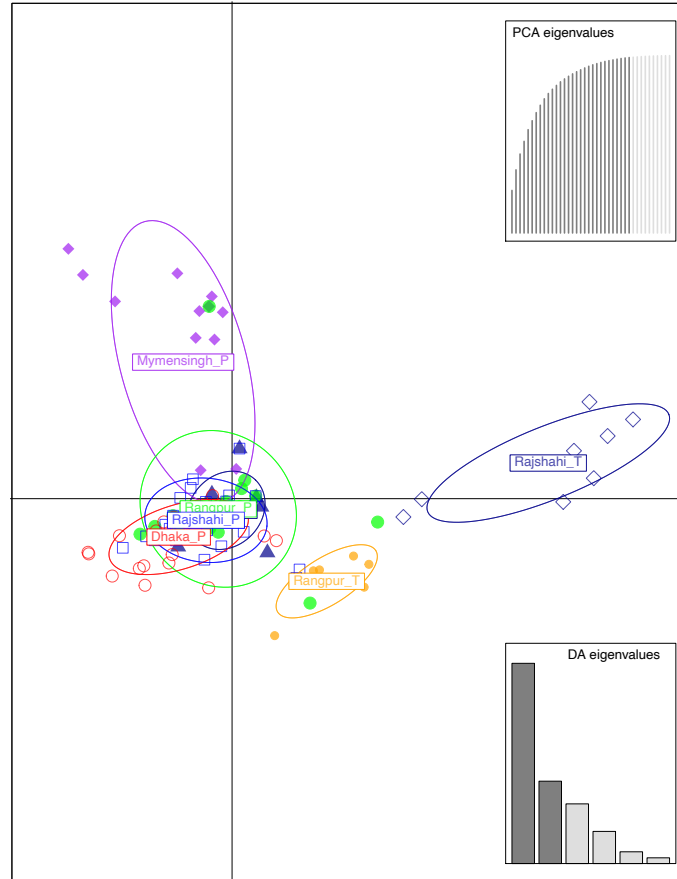


Figure 3. Discriminant analysis of principal components (DAPC) of *Phytophthora infestans* populations collected from five divisions of Bangladesh in 2018 (different letters P or T at the end of population stands for host potato or tomato, data analysed in R package poppr v. 2.3.0).

In Indonesia, microsatellite analysis of isolates collected from the main potato growing regions on the island of Java revealed that 60% of the isolates were EU_2_A1 or subclonal variants of EU_2_A1. However, 38% of the isolates were unique and clustered separately from European isolates and only one clustered with US isolates (Figure 4). The project also found 1.5% of isolates were EU_4_A1 or EU_13_A2. The genotypes EU_2_A1 and EU_4_A1 are older European genotypes which were dominant in Europe over 20 years ago and have since been replaced by EU_13_A2 as the dominant genotype. It is possible that EU_2_A1 is the original genotype that was introduced to Indonesia, and it is now being displaced in central and west Java by variants of EU_2_A1 and unique genotypes that were identified in these regions.

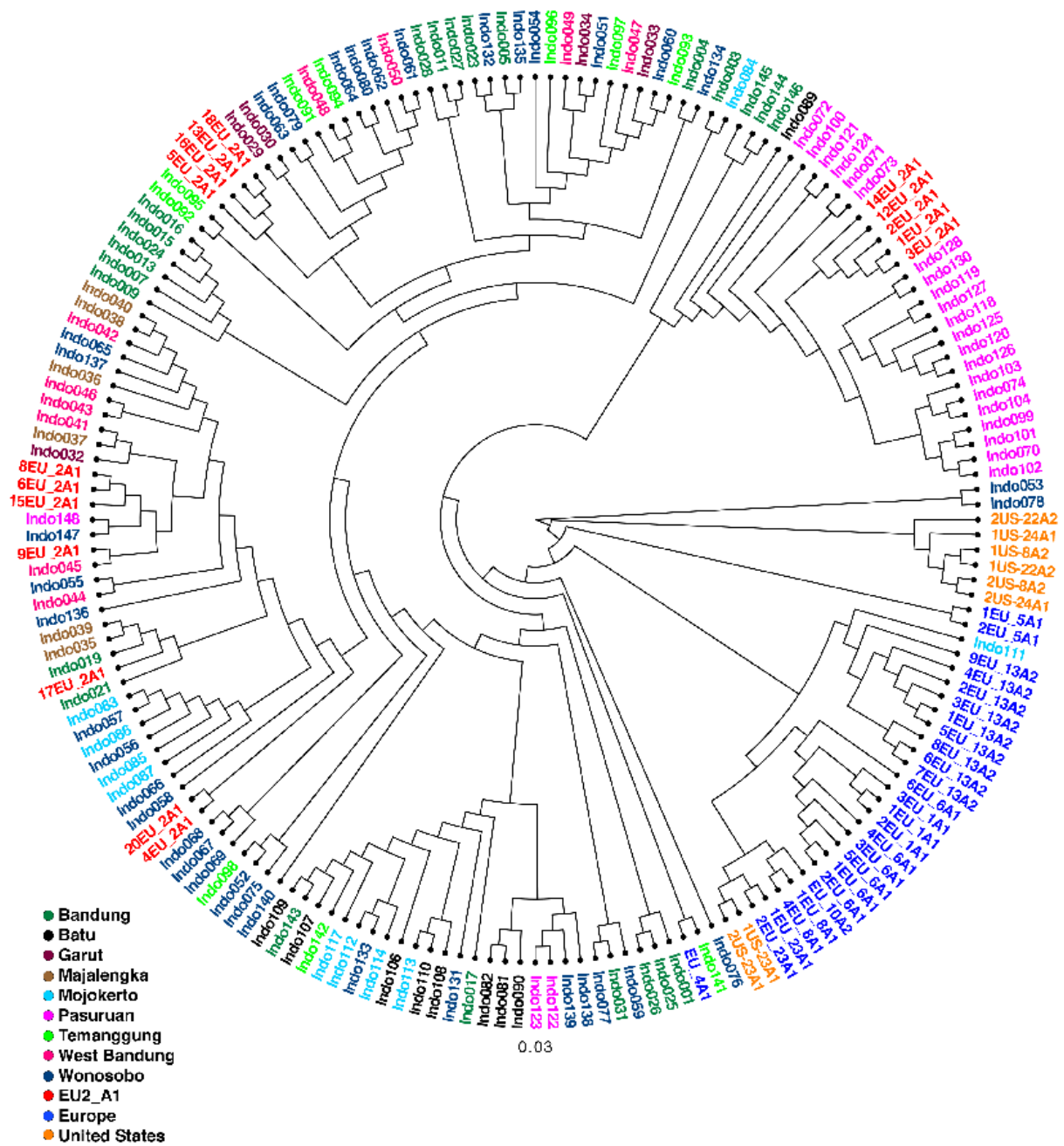


Figure 4. Neighbour joining tree based on Bruvo's distance for *Phytophthora infestans* populations from nine regencies in Java, Indonesia with 1,000 bootstrap replicates (data analyzed in the R package poppr V.2.3.0, results viewed and modified on Fig tree v1.4.3).

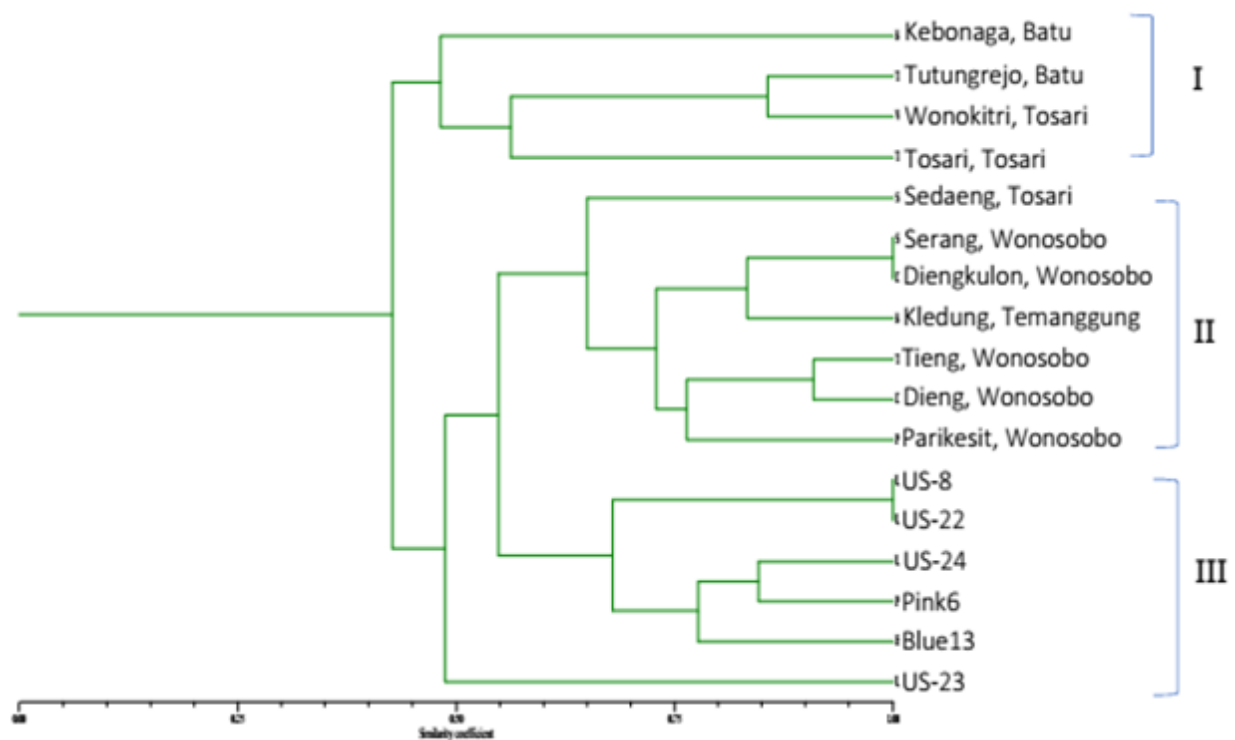


Figure 5. Clustering of 17 *P. infestans* isolates based on NTSYS 2.1 analysis. The clustering pattern clearly distinguished the Indonesian isolates from U.S. and Europe isolates.

Another accomplishment was a late blight isolate collection trip in the main potato growing regions on the island of Sumatra in Indonesia during FY2020. Understanding the isolates present in the different geographic areas is paramount. The isolates were the first to be collected by the team in this area expanding the collection area from the previous areas and providing invaluable information in the development of mitigation plans for LBR potato.

Results of this multi-year pathogen survey are presented in the [“Genotypic and phenotypic characterization of *Phytophthora infestans* populations on Java, Indonesia”](#), published in Plant Pathology.

The Bangladesh pathology team also achieved a major milestone with a successful isolate collection trip to every major potato growing district in the country in FY2020. Approximately 260 samples were collected on FTA cards. Bangladesh experienced very little late blight in the FY2019 growing season, hence, this collection was especially important.

Lessons Learned: Having a private sector partner, such as Simplot, provided the project with cutting edge technology with their vast resources and investments in state-of-the-art facilities and equipment that are often out of the reach of educational research universities and government-supported research groups. The access to these resources along with their scientific expertise and experienced personnel in biotechnology allowed the Biotechnology Potato Partnership to deliver 3R-gene LBR potatoes in two varieties that meet exceptionally high scientific rigor. This achievement was accomplished within a short project timeline that may not have been met without their involvement and commitment to the project.

An additional lesson learned is that the molecular characterization and final event selection process requires extensive research and testing. This extensive research and testing ensured the availability of comprehensive and accurate research data that will support product deregulation and comply with international GM product standards and regulatory guidelines.

Objective 4 – In conjunction with the International Potato Center (CIP) Kenya LBR potato project, test a 3R-gene LBR potato containing the RB, blb2, and vnt1 resistance genes in the Desiree variety in Indonesia and Bangladesh

Description: The Biotechnology Potato Partnership was also tasked with the additional mandate to conduct collaborative research on a USAID-funded 3R-gene LBR potato developed by Dr. Marc Ghislain of the International Potato Center (CIP) in Nairobi, Kenya. Dr. Ghislain transformed three varieties using a three gene stack consisting of the RB, *blb2*, and *vnt1* late blight resistance genes.

The International Potato Center (CIP) was founded in 1971 as a research-for-development organization with a focus on potato, sweet potato and Andean roots and tubers. It delivers innovative science-based solutions to enhance access to affordable nutritious food, foster inclusive sustainable business and employment growth, and drive the climate resilience of root and tuber agri-food systems. Headquartered in Lima, Peru, CIP has a research presence in more than 20 countries in Africa, Asia and Latin America.

CIP is a CGIAR research center, a global research partnership for a food-secure future. CGIAR science is dedicated to reducing poverty, enhancing food and nutrition security, and improving natural resources and ecosystem services. Its research is carried out by 15 CGIAR centers in close collaboration with hundreds of partners, including national and regional research institutes, civil society organizations, academia, development organizations and the private sector.

Both biotechnology potato projects, led by MSU and CIP, remain at the forefront of potato improvement research which provided a logical collaboration and partnership.

Activities and Results: During FY2016, Biotechnology Potato Partnership worked to ensure MTAs and other agreements were fully executed with CIP. Upon completion of these agreements, GM germplasm from CIP Kenya and Diamant from CIP was received by MSU along with the CIP Kenya 3R-gene LBR plasmid.

The three varieties transformed by CIP are Desiree, Victoria/Asante, and Tigoni. Of these, it was determined that the Victoria variety would be most suitable for testing in Bangladesh and Indonesia. This testing is designed to allow comparison of the resilience of the 3R-gene LBR potato and the 1R-gene LBR potato against late blight strains endemic to Indonesia and Bangladesh. Initial work plan activities included in-country greenhouse tests in FY2017, a single site confined field trial (CFT) in FY2018, and a multi-site field trial in FY2019. Overall, these trials for CIP's 3 R-gene LBR potatoes were designed to provide MSU breeders and pathologists information on various R-gene combinations and understand the propensity for pathogen evolution in the target countries. For in country-partners in Indonesia, this will allow them to compare the field performance of 3 R-gene LBR potato with the single R-gene LBR potato (Katahdin SP951 – Legacy Potato).

Due to the delay of material transfer agreements (MTAs) with partner countries and regulatory documents, the FY2017 work plan was shifted to testing of the CIP 3-R gene construct in a CFT at MSU's Clarksville Research Center in Clarksville, MI, U.S. MSU received the CIP 3-R construct in FY2016 from CIP Kenya. MSU also received tissue culture plants of Diamant which were imported into the U.S. and under a strict quarantine through the USDA. MSU was able to acquire the plants until testing and received USDA clearance. Therefore, there was a delay in transporting the Diamant variety to Simplot for transformation. To evaluate the transformability of Diamant, the MSU team decided to run a proof of concept experiment.

Once the construct, pCIP99, was received by MSU from CIP, it was transformed into the Diamant variety (the farmer-preferred variety in Bangladesh). Fifteen Diamant transformed events were tested. The events were compared with non-transgenic Diamant variety, non-transgenic Atlantic variety, and Katahdin SP951 also known as the single gene LBR Legacy Potato. All 3R-gene events except DiaCIP99.12 showed high levels of resistance to late blight. The single gene Legacy Potato showed little resistance to late blight. See Figure 6. It was useful to show this successful proof of concept experiment and field trial with our in-country partners.



Figure 6 (a-e). Performance of MSU Diamant CIP99 (DLACIP99) events inoculated with US23 *P. infestans* vs. non-transgenic potatoes and single R-gene LBR potato. (a) border rows: Atlantic (non-transgenic) (2 on left, 2 on right); center 4 rows include, Diamant, Katahdin SP951, and DLACIP99 events. (b) Close-up pictures of Atlantic (non-transgenic), (c) Diamant (non-transgenic), (d) Katahdin SP951 and (e) DLACIP99 events.

Also, during FY2017 the project received disappointing news from Bangladesh research partner BARI, that the Government of Bangladesh (GOB) had declined to receive the CIP 3R-gene LBR Victoria variety for research purposes. The decision was largely based on the fact that the variety, Victoria, is not popular with Bangladesh potato farmers and the GOB preferred to focus their research efforts on the single gene LBR Legacy Potato.

In addition, the proposal and dossier supporting the resistance evaluation of 3 R-gene LBR potato from CIP in the greenhouse (biosafety containment) was also completed and submitted to the Indonesian Agency for Agricultural Research and Development. Similarly, as with the Legacy Potato, a review on the progress and challenges of the deregulation of CIP's 3-R-gene events was also made during FY2018. The Project Team with approval from the TAB, decided to discontinue CIP-related activities due to delays in the importation of the material to Indonesia that will result in similar timing for CIP's and Simplot's 3 R-gene potatoes CFTs in country, and the lack of molecular characterization of the CIP 3 R-gene construct. Activity on this objective was completed in FY2018.

Lessons Learned: The collaboration with CIP provided the project insights into how other research teams work with biotechnology and transgenic materials. The Biotechnology Potato Partnership was able to build a strong relationship with CIP which provided the project with like-minded colleagues and a powerful and well-respected ally.

The project determined in the end that it is best not to have multiple constructs for the same trait in a country as this may confuse the national regulators, industry, and the public especially when the country is new to genetic engineering. The main purpose was to have in-country personnel gain experience. This led to a very useful idea which was to conduct in-country “simulated” confined field trials. This is detailed in our capacity building objective 6 and 7. Additionally, the efforts made regarding the proof of concept experiment and CFT trial conducted at MSU were very useful in explaining and encouraging the technology with in-country scientists and government officials.

Objective 5 – In conjunction with Venganza Laboratories, test the resilience of RNAi technology in the Katahdin variety at MSU

Description: The biotechnology potato partnership was also tasked with collaborating with the Venganza, Incorporated, a plant biotechnology company based in St. Augustine, FL. Venganza advances proprietary technology (RNA interference-induced pest gene silencing) for genetically engineering crops that are resistant to multiple pests. This collaboration consisted of field-testing RNAi technology in the Katahdin variety (as supplied by Dr. Walter De Young of Cornell University) and in SP951 Katahdin variety (Legacy potato), transformed with the RB gene.

Activities and Results: During FY2016, Biotechnology Potato Partnership worked to ensure MTAs and other agreements were fully executed with Venganza. Upon completing these agreements, over 80 RNAi events for field trials were sent to MSU in collaboration with Walter DeJong at Cornell University for the FY2016 field season. A confined field trial was conducted to assess foliar resistance of the 80 RNAi events and empty vector lines. A US23 isolate was grown in the lab and was used to inoculate the foliage in late July and mid August. Infection occurred later than normal due to the hot dry summer weather. Most events were susceptible but eight events that showed some resistance were scheduled to be retested in detached leaf bioassays during FY2017.

The Katahdin and SP951 events with RNAi constructs developed by Venganza, Incorporated were field evaluated at MSU during FY2017. These events used Venganza’s proprietary technology, RNA interference-induced pest gene silencing, for genetically engineering crops that are resistant to multiple pests. All transgenic potatoes containing Venganza RNAi constructs were tested for resistance to late blight using detached leaf bioassays (DLB) and a confined field trial. The US 23 isolate of *P. infestans* was used for the assessments. The lines were found to be susceptible and lacked synergistic resistance when combined with SP951 (*Figure 7 a-i*).

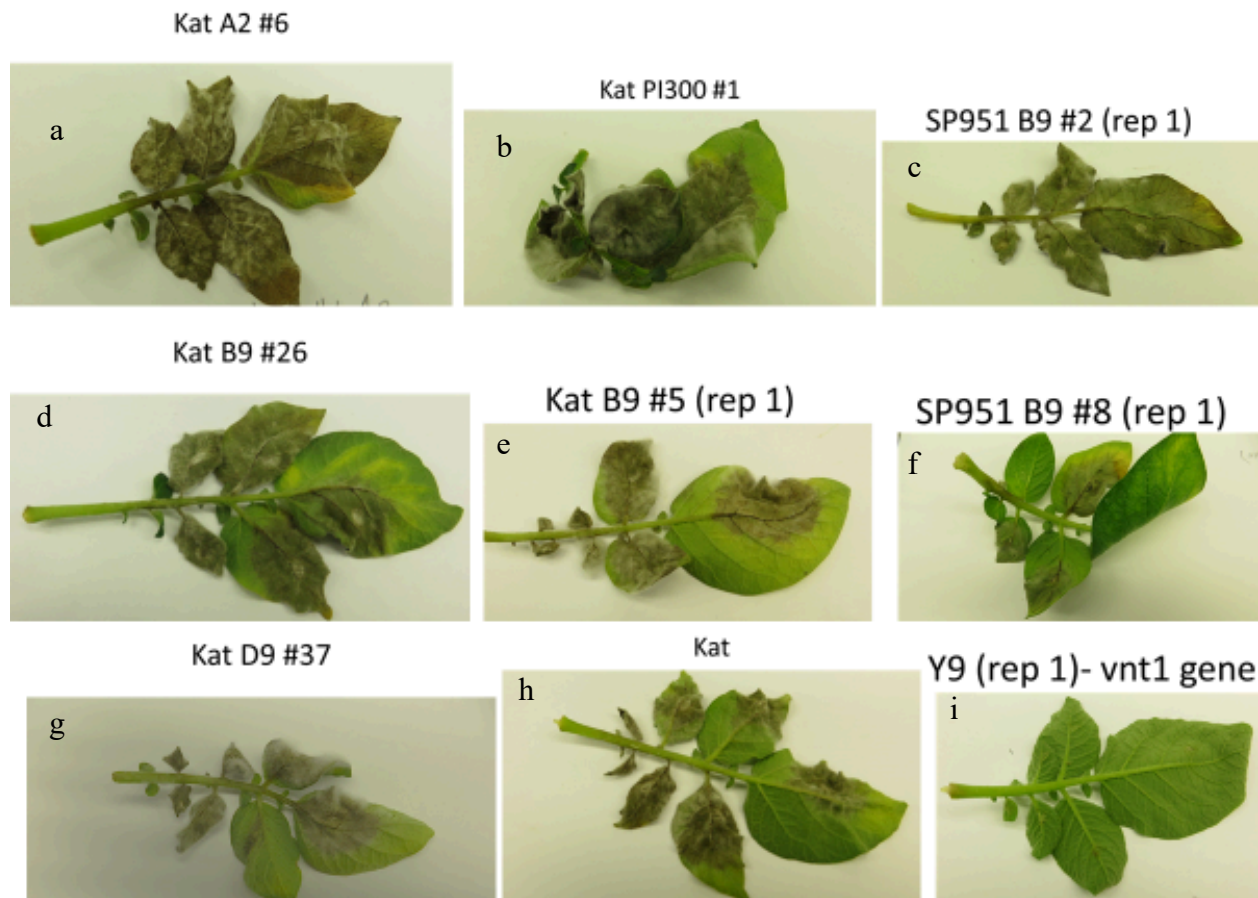


Figure 7 (a-i). Leaves of the transgenic potatoes containing *Venganza* RNA-i constructs and subjected to DLB to test resistance to late blight. The lines containing the *Venganza* constructs were found susceptible to *P. infestans* (a-g) when compared to susceptible untransformed controls (h) and other transgenic lines, such as SP951, which was susceptible and a transgenic Y9 event from Simplot (i), which was found to be highly resistant.

Venganza reassessed these transgenic events that did not result in late blight resistance in DLB at MSU. They validated using additional PCR analysis of the sense, antisense and intron segments separately and sequenced the amplicons. Results indicate that the potato transgenic events were transformed as expected with the four constructs, and there were no host or bacterial modifications of the construct sequences. The constructs were, however, found ineffective because of excessive editing of the native *P. infestans* sequences that were done to avoid off-target hits. Venganza submitted a report to USAID that details an explanation of the inability of the edited essential gene sequences to control *P. infestans*. Activity on this objective was completed in FY2017.

Lessons Learned:

It is important to test and evaluate new and promising technology options such as the RNAi technology. Connecting the research with practical testing provided a valuable assessment. This initial version of the RNAi technology was not effective. This allowed USAID to make decisions on whether to continue to explore this technology.

Objective 6 – Build the biosafety capacity of partner institutions in Indonesia and Bangladesh

Objective 7 – Build the scientific capacity of partner institutions in Indonesia and Bangladesh

Description: The Biotechnology Potato Partnership built regulatory and biosafety capacity in partner institutions (Objective 6) through quality management systems, work-based training, and biosafety audits. The project ensured that all biotech potato R&D was conducted in compliance with internationally accepted practices standards and national biosafety regulations.

The project also built institutional scientific capacity in partner institutions (Objective 7) in various areas including tissue culture, pathology, and microbiology.

The overall HICD goal of putting a research team in place in each target country that would have the necessary skills and infrastructure to facilitate the successful adoption and commercialization of a 3R-gene construct providing resistant to late blight disease in farmer preferred varieties.

Activities and Results: A robust HICD plan was developed in FY2016 to ensure the Biotechnology Potato Partnership built lasting capacity of researchers and institutions regarding regulatory biosafety research as well as scientific capacity. This plan began with a baseline study to establish the existing human scientific capacity (tissue culture, pathology, and microbiology) and the institutional capacity (availability and conditions of laboratories, greenhouses, and field facilities) of our partner institutions. The Knowledge Survey used as a part of the baseline assessment can be found at Annex V.

The training program for the core scientific team and the institutions of which they are a part, spanned the entire length of the project and used a tested and true training method known as “experiential learning” ([Kolb & Kolb, 2005](#); [Kolb, 2014](#)). This method utilizes a basic strategy which consists of modeling behavior, engaging participants in behavior, and then observing participants exercise the behavior. This was vital for the Biotechnology Potato Partnership since the acquisition of these skills prior to the testing of the GM product was vital for successful project outcomes.

In effect, the scientists that comprise the core technical team had the opportunity to “practice” the implementation of the product testing prior to the arrival of the LBR product by working with existing non-transgenic material. The initial training process of the core technical team consisted of three phases.

In the first phase, the core technical teams would participate in a growing season at MSU. This provided an opportunity to work side by side with MSU scientists in the basic skills and knowledge necessary for successful plant breeding, pathology analysis and mitigation strategies, seed production, and harvest. The microbiologists worked side by side with laboratory scientists to acquire the basic skills necessary for genetic analysis, characterization, and modification. The learning objectives for this training were:

1. The trainees will be able to identify biotechnology tools that can be used to improve the efficiency of a potato breeding program
2. The Breeders, Pathologists and the Molecular Biologists will be able to recognize each other’s roles and responsibilities in the potato-breeding program when they return to their respective countries and specifically in the Biotechnology Potato Partnership (Building Teams for Building Trust).
3. The trainees will be able to differentiate the scale of operation of US potato farmers vs. potato farmers in their respective countries.
4. The teams will be able to relate to the importance of having a bank of tissue culture lines for the LBR potato as well as a bank for the LBR isolates in their respective countries.

5. The teams will be able to establish a potato mini tuber production facility to produce clean material for LBR greenhouse and field research.
6. The breeders and the pathologists will be able to obtain late blight disease scores using standardized phenotyping protocols. The molecular biologists will also gain a working knowledge of disease phenotyping for late blight.
7. The molecular biologists will gain hands-on experience in transforming potato lines using existing gene constructs, which will enable them to perform plant transformation activities in their respective countries. The Breeder and the Pathologists will also gain a working knowledge on the plant transformation protocols and best practices.
8. The teams will be able to perform, collect and analyze data from greenhouse and field experiments comparing the one-gene and 3-gene LBR potato lines.
9. The teams will have a working knowledge on the environmental biosafety aspects related to LBR potato including best practices.
10. The teams will have a working knowledge on evaluating components of a Biosafety Dossier for commercial release.
11. The teams will be able to translate the LBR potato breeding activities at MSU and J.R. Simplot company to peers in their respective countries through a “Training of Trainer” (ToT) approach.
12. The teams will be able to appreciate the transparency maintained in the Biotechnology Potato Partnership and value the opportunities created through public/private sector partnerships in the US.
13. The teams will have an opportunity to practice what they learned at MSU using the LBR lines with the 3-gene construct from CIP (Kenya) until the new 3-gene construct is available from the J.R. Simplot company. This will provide the trainees an opportunity to apply the knowledge gained in the US while training others in their respective institutions through workshops.
14. The Teams will be able to analyze and inform project partners on progress made in their respective countries and suggest activities for way forward so that project goals are met.

The second phase was developed as a “practice” run for the three gene potato. Consisting of developing adequate research, stewardship, tracking, material handling, and data recording and analysis skills using non GM potato so that the core technical team is in place and ready to receive the three R-gene LBR potato upon development of the successful lines by Simplot.

The arrival of the Simplot material in Indonesia and Bangladesh was scheduled to be the third phase of the training process. By this time, the core technical team would have had opportunity to refine their skills and be in a position to adequately handle and carry forward the projects key activities, resulting in the successful field testing of the project’s own 3R-gene LBR potato.

Baseline visits by the U.S. team to partner institutions and knowledge studies were an important achievement during FY2016 that helped to modify the designed training program noted above. These visits and studies identified that the Indonesian team was more advance than the Bangladesh team in the technical sciences. Modifications were made to the first phase which included a shorter training period in the U.S. for the Indonesian team. Unfortunately, these U.S. trainings were delayed until FY2017 once the project team realized the planning time to bring these researchers to the U.S. was extensive.

HICD activities did however take place during FY2016, as the team developed a capacity building program for partner countries technical teams focused on the scheduled import of the CIP 3R-gene LBR potato material. This training included receipt of GM material, design and implementation of greenhouse trials, seed production, and data collection.

A workshop was held in Indonesia during the second quarter of FY2017. The location was selected for three reasons.

1. The Bangladeshi team was easily able to obtain visas for travel to Indonesia.
2. To showcase how the Indonesian team was moving the single gene late blight resistant Legacy potato forward.
3. To connect the teams for peer-to-peer learning and to build cross country relationships.

The workshop facilitated three interaction and exchange of experiences among partner institutions and experts involved in the Biotechnology Potato Project. Participants included: project personnel from MSU and UMN; partners from University of Idaho and Perseus BVBA; USAID Bangladesh Mission, Bangladesh core technical team from BARI and Indonesian core technical team from ICABIOGRAD. Approximately 50 participants attended the opening day of the workshop. See Appendix VI for workshop agenda.



Training Workshop for participants of the Legacy potato and Feed the Future Biotechnology Potato Partnership projects held from January 23 – 26, 2017 in ICABIOGRAD, Bogor, Indonesia.

A follow up intensive training of the technical core teams from Bangladesh and Indonesia was carried out at MSU in summer 2017 (Figure 8 a-c). The plan for this training was guided by the knowledge survey done in October 2016, results of evaluation of the training workshop held in January in Bogor, Indonesia, advice from USAID AOR on training follow up and sustainability, and best practices in training and capacity building.



Figure 8 (a-c). Intensive HICD training at MSU for Bangladesh and Indonesian scientists. (a) Bangladeshi scientists replant tissue-cultured potatoes for mini-tuber production using nutrient film technique. (b) Project Director Dr. David Douches, with the in-country scientists, replant transformed plants for CFT in Clarskville, MI. (c) Bangladesh and Indonesian scientists together listen to Dr. Phill Wharton's lecture on *P. infestans* infestation.

Specifically, the plan highlighted a “learning by doing” approach and offers technical and practical laboratory, greenhouse, and field skills to the scientists of both countries. Training was specifically tailored for each individual with the goal of getting them to understand their specific role for delivering the expected outcomes of Biotechnology Potato Partnership. The training content and materials were also designed so the scientists trained at MSU can share them with their colleagues when they return. The training featured a strategic mix of lectures, hands-on laboratory and field activities, interactive discussions, knowledge, and experience sharing with technical team members from MSU, U of I and UMN. Practical site visits were taken to MSU's CFT trials in various locations in the state of Michigan, and Simplot corporate headquarters in Boise, ID. Table 5 provides information about the participants, research area and dates of their training at MSU.

Table 5. Bangladesh and Indonesian core scientists and participants for Biotechnology Potato Partnership training at MSU.

NAME	AFFILIATION	AREA OF TRAINING	DATES OF TRAINING*
1. Md. Shafiqul Islam	TCRC, BARI	Potato breeding/ Molecular biology/Regulatory	June 15 – September 30, 2017
2. Fahmida Akhter	TCRC, BARI	Tissue culture, Molecular biology	June 15 – July 25, 2017
3. Md. Musfiqur Rahman	TCRC, BARI	Pathology/ Regulatory	June 15 – September 30, 2017
4. Dr. Alberta Dinar Ambarwati	ICABIOGRAD	Biotechnology/ Regulatory	August 9 – August 29, 2017
5. Dr. Edy Listanto	ICABIOGRAD	Molecular biology/ Regulatory	August 9 – August 29, 2017
6. Dr. Tri Joko Santoso	ICABIOGRAD	Molecular biology/ Regulatory	August 9 – August 29, 2017
7. Dr. Ineu Sulastrini	IVEGRI	Crop protection/ Regulatory	August 9 – August 29, 2017
8. Kusmana	IVEGRI	Crop protection/ Regulatory	August 9 – August 29, 2017
9. Dr. Muhammad Herman		Regulatory	August 23- August 29, 2017

*These dates were adjusted after U.S. visa issuance and to accommodate availability of the scientists and trainers.

FY2018 capacity efforts continued to build both the biosafety and scientific capacities of our partner institutions. The project prepared for the implementation of a ‘mock’ field trial to train and build biosafety capacity of BARI and ICABIOGRAD in conducting field trials under confined conditions that meet regulatory guidelines. Mock trials, using non-biotech potato materials, along with simulating field conditions, will also test the efficiency of biosafety procedures, regulatory compliance and oversight that will occur in actual CFTs for the 3 R-gene materials.

The preparation for the mock field trial, scheduled for FY2019 of the project, was complemented with the design of study plans; and development and training on SOPs for biosafety compliance in CFTs. The mock trials, using non-biotech potato materials, along with simulating field conditions, tested the efficiency of research procedures, regulatory compliance and oversight that will occur in actual CFTs for the 3 R-gene LBR potatoes. The study plan includes information on the plant materials, field sites, experimental design, agronomic practices, data collection and analysis, and records that need to be maintained.

On the other hand, the draft SOPs provide guidance on biosafety for critical activities in CFTs including compliance at the institutional and individual researcher levels, identification and inventory of plant materials, transportation, shipping and receipt of materials, planting of GM potato field trials, harvest of materials and post-harvest management of field trial sites for GM potatoes and reporting of incidents and corrective actions.

Physical visits, discussions, and virtual follow-up with in-country researchers in BARI and ICABIOGRAD were done during FY2018 to enhance understanding, appreciation, collaboration, feedback, and use of these SOPs. As needed, retooling of in-country researchers on these SOPs, and rewriting these SOPs to cover new tasks or situations that have been anticipated and will continue to be provided. Meanwhile, regulatory planning for transfer and deregulation of Simplot’s 3 R-gene event in Bangladesh and Indonesia, also started this year.

Access to technology and knowledge transfer support continued to be provided to BARI and ICABIOGRAD throughout FY2018 and FY2019 to help build their scientific capacity in areas of tissue culture, pathology, microbiology, and all other activities related to biotech potato research and development.

ICABIOGRAD made great progress in many of its research experiments related to pathogen genotyping and completed them during FY2018. More capacity building was required for BARI researchers for isolation and culture of *P. infestans*. Optimization efforts and contingency plans were suggested for successful pathogen isolation and quantification of late blight resistance of potato crops in Bangladesh and the BARI pathologist mastered the necessary skills.

To help enhance scientific productivity and capability of BARI researchers to conduct experiments, support was also provided to upgrade BARI's tissue culture lab. The renovation of the tissue culture lab of BARI was completed during FY2018, including inspection by Bangladesh's National Technical Committee on Crop Biotechnology, and was certified GM-compliant by the country's Ministry of Agriculture in FY2019. The project provided inputs to the renovation design, including required laboratory components, and laboratory reagents and chemicals were also purchased by the project.

The project designed and developed a detailed 'test run' training manual to conduct a 'test run' for tissue culture, micro propagation, greenhouse tuber production, and basic molecular biology and pathology activities that support the research on of biotech potato materials. The 'test run' allowed documentation of the capacity of in-country partners to conduct aforementioned activities and deliver expected outcomes for the 3 R-gene LBR potato. The 'test run' manual provides step-by-step instruction on activities that need to be conducted and documented in the form of a checklist.

Specifically, the 'test run' manual has five parts covering media preparation, handling new plant material, tissue culture micro-propagation, molecular identification of potato lines sent to partners and technical expertise needed to isolate and culture the late blight pathogen. This manual, including the non-biotech tissue culture plants from MSU, DNA extraction kits and other materials needed to conduct the activities were sent in FY2018 to in country partners in Bangladesh and Indonesia to start review and implementation. Both BARI and ICABIOGRAD carried out the activities in the 'test run' manual considering they are handling genetically modified materials.

Project leads in both partner institutions were assigned as 'leads' in the monitoring and reporting of progress of implementation of the 'test run' and other technical activities for BARI and ICABIOGRAD, respectively. Bi-monthly virtual meetings are held to obtain feedback on the progress of activities. Activities under the program continued throughout FY2019 and FY2020. In FY2020 the project analyzed the final data from the 'test run' activities and renamed the materials, GM Capacity Building Manual. A manuscript showcasing learning and best practices on plant biotechnology HICD was completed and published as a book chapter. ["Case Study: A Roadmap for Developing Capacity in Plant Biotechnology Field Research"](#) appears as Chapter 2 in the book, *Current Topics in Agricultural Sciences Vol. 1*.

The arrival of the COVID-19 pandemic during FY2020 shifted many HICD activities from in person to online formats. Travel restrictions cancelled a planned training for the Bangladesh core technical team in Indonesia to work alongside Indonesian counterparts as they implemented a 3R-gene LBR CFT.

Other HICD efforts of the project included a training workshop in FY2018 on Best Practices in Survey Administration was conducted for four (4) scientists from IVEGRI to enhance their skills in survey methods and adopt best practices in human subjects research. Such research is important to understand the social science impacts when introducing new technologies.

In addition, as the Biotechnology Potato Partnership's HICD efforts grew, an interactive HICD dashboard was developed in FY2019 to provide a snapshot of the important activities and progress in this area. The dashboard was featured on the project website.

Regulatory Biosafety Capacity Development

It is important to note that a large portion of the biosafety capacity development intricately involved issues related to understanding and navigating each country's biosafety regulatory framework, as well as international biosafety standards. In addition, the scientific capacity built also needed to be viewed through a biosafety regulatory framework lens. Throughout the development and implementation of biosafety HICD efforts, the Biotechnology Potato Partnership's Regulatory Lead provided expert guidance to ensure that efforts in both biosafety and scientific trainings met international standards for biotechnology.

Lessons Learned:

A holistic HICD approach supported with practical and cost-effective training plan is needed to ensure capacity development for biotech activities yields performance improvement. Building human and institutional capacity for biotech needs a broader commitment beyond the training and requires addressing the broader institutional performance gaps to result in individual or institutional performance. Other lessons learned include:

Base requisite knowledge: For projects, trainees, and institutions to benefit from experiential learning, there has to be a threshold of base knowledge present in the trainees. Some form of pre-test or qualifying exam should be part of the experiential learning process for there to be a sufficient base on which to scaffold new knowledge. In our case, we had to dismiss two of the ten trainees for lack of adequate base knowledge. The time, effort, and cost of their training, in the end, were lost since the trainees were never able to integrate new knowledge into their existing base knowledge.

Prolonged training as well as mentoring and coaching: Our original timelines were too short. Although the five-month training was extensive and very valuable for our trainees, in the end, it was clear that we should have planned on a longer and more rigorous process. Even using the best of experiential learning techniques, a learning process of two to three years should be assumed to inculcate fully the principles needed for the safe and effective conduct of GE trials as well as the ability to successfully face and overcome unexpected obstacles. In addition, we found the need to have ongoing mentoring and coaching programs in place that allow for continual oversight. Even though the last stages of the live GE trial, there were still points that needed reinforcement and repetition.

Frequent evaluation: One of the more effective adaptive practices that we established by way of necessity in the conduct of this training was the introduction of evaluations. This provided two important components of the experiential learning process. First, it allowed for frequent formative evaluation, giving us insight into how well the trainees had grasped the concepts that we had shared. This was especially important because we were working across cultures and languages.

Simulated trials: We would highly recommend at least one simulated confined field trial using non-GE materials in a no-risk environment during the initial implementation of a biotechnology project. Most of the deep learning took place in the course of these trials and it was surprising to see and learn what important misunderstandings remained after the extensive training had been undertaken. Some of these issues would have made moot the trial results or would have produced a high risk for non-compliance to regulations had it been at the time a trial with the actual GE plants. We now consider a simulated trial to be a core component of effective plant biotechnology field research training and the implementation of biotechnology projects.

Objective 8 – Improve gender balance in partner institutions

Description: The Biotechnology Potato Partnership ensured that technological adoption and use was gender neutral. The diverse gender roles were identified and understood clearly through a participatory process.

Activities and Results: The Biotechnology Potato Partnership ensures that technology adoption and use are gender neutral. The project also continues to ensure that activities in research, capacity building, and outreach continue in a gender-responsive way.

The Indonesian core technical team had a total of five members, two were women including the Principle Investigator and the Pathologist. During the course of the project in Bangladesh, the project worked with two separate core technical teams. The first team which was managed out of BARI's Tuber Crops Research Center (TCRC) and contained four scientists, two were women. The second team which took over during FY2020, was managed out of BARI's Biotechnology Division and contained five scientists, two were women. To view the in-country core technical teams, please see Annex VII.

The project also works to ensure that there is equal participation of women and men in short-term training, workshops, and other events sponsored by the project.

Lessons Learned: The project had always placed high expectations on creating a diverse team and understood the importance of gender. This expectation served the project well as the diverse core technical teams were critical to the success of the project.

Objective 9 – Demonstrate the socio-economic benefits of 3R-gene LBR potatoes

Description: The project focused on understanding the socio-economic impacts of modern biotechnology in relation to technology acceptance, affordability, adoptability, gender equity, appropriateness, and economic and communal implications as well as socio-economic considerations in biosafety decision-making.

Activities and Results: Understanding of the socio-economic factors affecting the potential impact of the single gene and the 3R-gene late blight resistant potato are critical for project success. The socio-economic component of the Biotechnology Potato Partnership was focused on three impact areas:

1. Economic impacts including improved income for male and female potato farmers in Bangladesh and Indonesia, and spillover effects into the agribusiness sector.
2. Social impacts including improved food and nutritional security amongst male and female members of the households that have adopted the new potato varieties in Bangladesh and Indonesia, and gender-neutral access, adoption, productivity, and use of the new potato varieties by farmers in Bangladesh and Indonesia.
3. Environmental impacts which include a reduction in the use of toxic agro-chemicals on the farm ecosystem, and a reduction in exposure to these materials.

Impact assessments encompassing socio-economic and environmental considerations are important to determine the costs and benefits associated with biotech potato in comparison to alternative technologies and to encourage acceptance of the innovations by farmers in project countries.

To understand the current state of potato in each country, the project conducted extensive literature reviews and interviews of in-country collaborators. Partnerships were formed with local economists from BARI and ICABIOGRAD to design and execute a socio-economic evaluation. The project hit stumbling blocks in delayed Institutional Review Board (IRB) training and certification of in-country partner experts as required by MSU. This along with other unexpected delays pushed the scheduled data collection into FY2019.

The initial socio-economic strategy was ultimately replaced with a new workplan that included an extensive literature review of peer-reviewed journals, reports, and national statistics in FY2019 that profiled the potato systems in both partner countries regarding production, consumption patterns, and trade. The result titled, *Evaluating Potential Socio-economic Impacts of Late Blight Resistant Potato in Bangladesh and Indonesia: Rationale, Research Protocol and Work Plan* included three ex-ante studies:

1. Deriving financial costs and returns
2. Measuring technical efficiency at farm-level
3. Modeling cost-benefit analysis

Lessons Learned: One challenge the project faced was that activities took much longer than anticipated, in part due to IRB guidelines and University regulations. It is important to understand human subject study guidelines and build adequate time into workplan activities to account for procedural approval delays.

Objective 10 – Advance the knowledge of the scientific community regarding GM late blight resistant potatoes

Description: The Biotechnology Potato Project produced scholarly publications and presentations related to the use, dissemination, and deployment of modern biotechnology.

Activities and Results: Project team members attended many global scientific conferences and workshops annually. At many of these events, Biotechnology Potato Project personnel also gave presentations and talks, participated and/or led panel discussions and plenary sessions, and presented posters. A complete list of these activities can be found in Annex VIII – External Scientific Presentations.

The project also produced five peer reviewed scientific publications and expects additional publications to be generated from the final data and research. The scientific publications can be found in Annex IX.

Lessons Learned: Putting scholarly articles on open access journals can provide an opportunity for wider readership. This can be especially true during times of crisis, such as the COVID-19 pandemic. During the pandemic much research was paused. The project feels this pause in active research led many scientists to spend idle online learning about other's research.



Biotechnology Potato Partnership project personnel present on the 3R-gene LBR potato at global conferences, workshops, and events.

Objective 11 – Effectively communicate project achievements and benefits of the GM potato to project personnel, stakeholders, and the public

Description: The project generates publications and messaging targeted to internal and external audiences. External messaging is focused on the promotion of the value and safety of modern biotechnology in agriculture. Internal communications focused on project personnel are designed to achieve knowledge sharing across area of project expertise and keep project personnel informed on day-to-day project activities, progress, and challenges.

Activities and Results: The Biotechnology Potato Partnership identified clear activities to reach this objective. These included:

- Development of project communications strategy including target country strategies. See Annex X.
- Development and maintenance of project website hosted by MSU at <https://www.canr.msu.edu/biotechpp/>
- Development and maintenance of social media accounts
 - Twitter @FtFpotatopjt <https://twitter.com/FtFpotatopjt>
 - Facebook found @ Feed the Future Biotechnology Potato Partnership <https://www.facebook.com/>
- Promote research highlights through electronically distributed newsletters
- Create project fact sheet and collateral materials
- Publish quarterly, semi-annual and annual reports and make publicly available
- Write news articles, features, and stories for submission to general audience media outlets. See Annex XI.
- Participate in outreach activities such as biotechnology media events and workshops
- Create library of materials to aid in project storytelling including photographs and videos
- Build a network of collaborative organizations working in biotechnology communication and advocacy
- Development of internal communication structure for information sharing between project team members

During FY2016 many of the communications activities were initiated including strategy development, project fact sheet, website design, internal communications structure, and project reports. In addition, as a part of the communications strategy, in-country communications coordinators were identified and contracted to help lead country specific activities.

A Communications Workshop for biotechnology stakeholders in Bangladesh was co-hosted with the Feed the Future Southeast Asia Bt Brinjal Project during FY2017. This workshop aimed to identify communication needs and develop a comprehensive communications strategy to support Feed the Future biotech projects in Bangladesh. The workshop also featured a stakeholder's meeting attended by more than 45 participants that provided project team members, government officials and research leaders from BARI, Department of Agricultural Extension, Ministry of Agriculture, and representatives of other biotech projects in Bangladesh an opportunity to interact and discuss priorities.

Social media efforts combined with the project website, newsletters and feature articles were the primary vehicles the project used to reach external audiences. The project also tested the effectiveness of maintaining a Twitter account in Bahasa, the local Indonesian language. It was determined that although the site did receive some traffic, it was cost prohibitive to dedicate the manpower necessary to effectively maintain the account. Analytics were used to regularly monitor all social media accounts to ensure they were performing at or above industry standards.



Twitter accounts in both English (above) and Indonesian Bahasa (left) provided a good opportunity to promote the benefits of GM technology to the general public.

Building strong collaborations with other organizations involved in biotechnology communication and advocacy was key to the project's communication strategy. Biotechnology and GMOs elicit strong emotional responses among and within different stakeholder groups. Millions in dollars are spent annually by anti-GMO groups, often backed by large corporations and NGO's to discredit the science behind the technology. These groups often use fear as a messaging strategy and spread non-scientific misinformation. They are very active in mainstream media and recruit many followers. To counteract these efforts, pro GMO advocates have worked together to develop and educate groups on the benefits of biotechnology. Often collaborating on messaging campaigns and strategies. The project was an active part of this collaborating group.

During FY2020 the project collaborated on a biotechnology consumer preference study in Indonesia. This was led by USDA-FAS Indonesia and executed by IndoBIC, the project's in-country communications coordinator. Such studies, as well as research conducted by collaborating partners and others, ensured the project was consistently reviewing messaging strategies and platforms to deliver the most effective communication for the project.

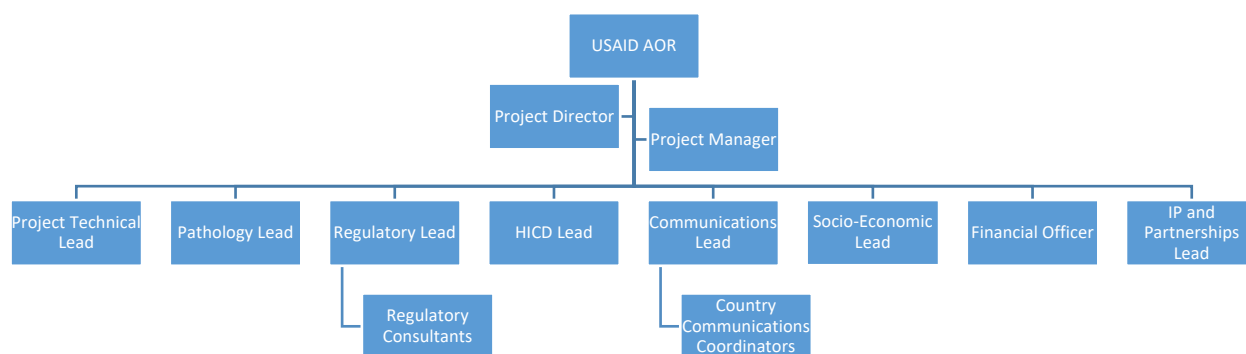
Lessons Learned: Anti-GMO groups often deployed strategies using fear-based messaging based on misinformation. This would lead to the project wanting to provide an immediate response to counter these claims. However, it was learned that this was usually not the best strategy, as it only served to continue the conversation and keep the misinformation forefront in consumer minds. It is better to be non-responsive and allow the conversation to fade naturally, then reintroduce positive fact-based GMO messaging at a later date.

PROJECT MANAGEMENT

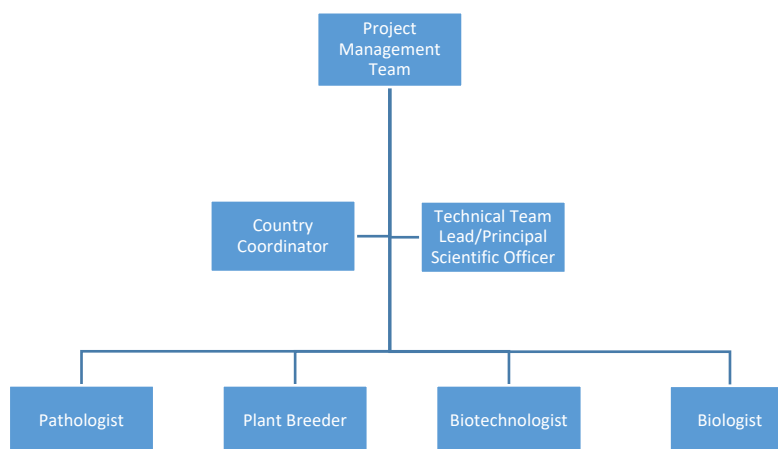
The Feed the Future Biotechnology Potato Partnership project management employed an adaptive management style throughout the project. This allowed the project to be effective, responsive, and provide a supportive environment.

Management activities were led by a program manager, reporting directly to the project director. The Program Manager was a key personnel position interacted with all components and areas of the project. The Biotechnology Potato Partnership adopted a team management approach as outlined by the following core project team organizational chart.

This structure was further supported by partner country teams as illustrated below.



This structure was further supported by partner country teams as illustrated below.



In addition, a technical advisory board (TAB) was developed to provide additional support to the project team. (*Annex II*)

The Program Manager worked closely with the Project Director to ensure all project activities and workplans were executed in a timely and acceptable manner. The Program Manager instituted file management protocols and implemented the project management software tool, Smartsheets, to manage day-to-day activities. Although the Program Manager oversaw the activity of area Leads, the position worked intricately with the Monitoring and Evaluation Lead, The IP and Partnerships Lead and the Financial Officer. A Project Management Plan was prepared and approved by the project's USAID AOR. The plan contained the metrics and indicators for regular review to help measure the project's progress and success.

Monitoring and Evaluation

Critical to the success of the project was the integration of monitoring, evaluation, and reporting systems. A Project Management Plan was prepared and approved by the project's USAID AOR. The plan contained the metrics and indicators for regular review to help measure the project's progress and success. A project dashboard was created to reflect all project activities, including success indicators, tasks for follow-up, and the financial status. An additional HICD dashboard was also created to provide the project with a visual display and up-to-date status of HICD activities. These tools, along with regular reporting as required by USAID allowed the project to stay on task.

A Monitoring, Evaluation, and Learning (MEL) plan was developed and implemented to serve as a guide for the project in this area. See Annex XII for the Biotechnology Potato Partnership's MEL plan.

REGULATORY AFFAIRS

Biosafety regulatory activities of the Biotechnology Potato Partnership crossed over into many of the project objectives and was integral to the success of the project. Understanding and navigating the biosafety frameworks in both Bangladesh and Indonesia were often complicated and lacked definition. In addition, the project was committed to building the regulatory biosafety capacity of in-country project partner organizations BARI and ICABIOGRAD. During FY2016 the project outlined four goals for the regulatory component of the project:

1. Lead all regulatory affairs for the project
2. Meet in-country regulatory requirements for the LBR potato
3. Prepare research applications for the different products and countries
4. Plan and collect data for the general release dossier

Among the first regulatory activities was to assess the regulatory capacity of all partners. The project engaged in dialogue with numerous groups including in-country coordinators and regulatory authorities, International Life Sciences Institute (ILSI)/ Center for Environmental Risk Assessment (CERA) South Asia Biosafety project in Bangladesh, the Program for Biosafety Systems in Indonesia, the regulatory team at Simplot, members of the Bt brinjal project working in Bangladesh, and personnel working in regulatory affairs for biotech projects on the Arcadia and International Rice Research Institute (IRRI) rice project in Bangladesh and Indonesia. It was realized that to meet the regulatory needs of the project, additional expertise would be required. The regulatory lead assembled a team of highly skilled regulatory consultants to assist the project (*see Annex I*). This team was particularly instrumental in the project's review and assessment of the Legacy potato regulatory data and dossier.

In order to accomplish the second regulatory goal, the project completed a thorough review of the regulatory requirements of GE products in both partner countries. This identified the complex structure of moving these products through the research and eventual commercialization stages. In addition, although parallel similarities existed, each country's regulatory framework had many nuances and as a relatively new

technology, many components had not been tested due to the limited GE research and development in the countries.

With an understanding of partner country regulatory frameworks, the project worked to gather and review existing SOPs within the project teams at ICABIOGRAD and BARI as it was important to know the existing capacities of each organization but also to ensure compliance with USAID requirements when working with GE products. Throughout the life of the project the Biotechnology Potato Partnership worked in tandem with in-country teams to review and revise biosafety SOPs to ensure they met international standards.

A major accomplishment of the regulatory component of the project was the establishment, training, and implementation of SOPs for biosafety materials that span from preparation for the receipt of the materials completely through CFT conclusion which encompass the complete research cycle. This training was a critical component of the project's HICD efforts and have left the teams at ICABIOGRAD and BARI well positioned to work with GE materials in a self-reliant manner.

The project also provided in-country partner organizations with the capacity to understand and navigate their country's regulatory framework as the project successfully obtained numerous import, quarantine, contained use, and CFT permits throughout the lifespan of the project.

COVID-19 PANDEMIC IMPACT

During the second half of FY2020, project management's main focus was how to safely and effectively continue research activity during a global pandemic with the onset of COVID-19. U.S. project members shifted from office/lab duties to restricted at-home work and international partners followed the directive of their respective governments to ensure a "safety first" edict. All travel (domestic and international) was canceled indefinitely which was held through the completion of the project.

The management team took care to follow USAID COVID-19 directives and guidelines and adjusted workplan activities based on these directives. The project continued to support all project personnel and provide necessary leadership and guidance.

The pandemic had a greater impact on activities in Bangladesh than in Indonesia as the project was in the middle of amending the MOU and attempting to shift the core technical team from BARI's Tuber Crops Research Center to the Biotechnology Division. Also, submitted regulatory documents were stalled as government offices closed.

The Biotechnology Potato Partnership worked closely with in-country core scientists throughout the project to build both biosafety and scientific capacities. Much of this work was done as in-person training events. The COVID-19 pandemic halted the in-person activities and travel which would have provided valuable interactions. The project re-established training through online formats however, the working side-by-side component was absent.

ENVIRONMENTAL MANAGEMENT AND MITIGATION PLAN (EMMP)

The project's EMMP was revised and approved on July 30, 2018. The plan, which is now integrated in the project's Monitoring and Evaluation (M&E) plan consisted of Initial Environmental Examination (IEE) conditions that will have to be met, mitigation and monitoring procedures and timing, and responsible parties. The EMMP covered five main activities and that include: 1) research with regulated GM potato in contained use conditions (laboratory or screenhouse/greenhouse research) in partner countries; 2) import of regulated GM potato into partner countries; 3) research with regulated GM potato in CFTs in partner countries; 4) use of pesticides in research trials under four (4) hectares in partner countries; and 5) commercial

release of GM potato. Monitoring included audit of laboratory and greenhouse activities, record of all training, record of material movement, audit of import activities, CFT, and pesticide use.

OPEN DATA MANAGEMENT PLAN

The project's data management plan, also integrated into the project's M&E plan, was revised and approved July 31, 2018. All data, analytical methods, and findings generated by the project are were packaged and shared freely available to the wider scientific community and have no restrictions. Preliminary project results are publicly shared through the biotech potato project's website, workshops and conference presentations and soon in peer-reviewed journal publications.

The project shared reports to USAID's Development Experience Clearinghouse: <https://dec.usaid.gov/dec/home/Default.aspx> as required by the USAID's open data policy. The project also shared data to the USAID's Development Data Library (DDL) <https://www.usaid.gov/data>. When appropriate, data generated by the program was deposited in an open-source research data repository (preferably Dataverse dataverse.org, or Mendeley: <https://www.mendeley.com/>) or other discipline-based repositories, if available, to help increase the project's research outputs' visibility and linked from the DDL. All these initiatives make the biotech potato program's outputs more discoverable by the scientific and research community but also encourage credit, attribution, and increased citation.

FINANCIAL

Please see Annex XIII

FUTURE OF LBR POTATO

The Biotechnology Potato Partnership's 3R-gene LBR potato has to date, been a success. Further R&D is needed to move this product closer into the hands of the smallholder farmers it was intended to reach. Project successes and learnings will contribute to the successful initiation and implementation of a new five-year cooperative agreement with USAID (Global Biotech Potato Partnership, 2021-2016). This new grant offers an expanded scope of activities on deregulation, product development, commercialization, and stewardship of biotech potato products in Asia and African countries.



ANNEX I – PROJECT PERSONNEL

Personnel	Area of Expertise	Organizational Affiliation
Dave Douches, PhD	Partnership Director	Michigan State University
John Medendorp, PhD	Program Manager	Michigan State University
Jane Payumo, PhD	Monitoring and Evaluation Lead	Michigan State University
Karim Maredia, PhD	Intellectual Property Lead	Michigan State University
Cholani Webadde, PhD	Human and Institutional Capacity Development Lead	Michigan State University
Hashini Galhena, PhD	Socio-Economic Lead	Michigan State University
Janet Fierro	Communications Lead	Michigan State University
Leigh Baker	Financial Lead	Michigan State University
Kelly Zarka	Technical Lead	Michigan State University
Karen Hokanson, PhD	Regulatory Lead	Minnesota State University
Phillip Wharton, PhD	Pathology Lead	University of Idaho
Jahangir Hossian, PhD	Bangladesh In-Country Coordinator	Feed the Future Biotechnology Potato Partnership
Md. Arif Hossain	Bangladesh Communications Coordinator	Feed the Future Biotechnology Potato Partnership
Mohammed Herman, PhD	Indonesia In-Country Coordinator	Feed the Future Biotechnology Potato Partnership
Dewi Suriyana	Indonesia Communications Coordinator	IndoBic
Monica Garcia-Alonso	Regulatory	Consultant
Natalia Bogdanova	Regulatory	Consultant
Vanessa Cook	Regulatory	Consultant
Mike Wach	Regulatory	Consultant
Bill Pilicinski	Regulatory	Consultant

ANNEX II – TECHNICAL ADVISORY BOARD

Name/ Organization	Biography	Dates Served
Joe Huesing USAID	Joe Huesing serves as the Senior Biotechnology Advisor and the Program Area Lead for Advanced Approaches to Combating Pests and Diseases at USAID. He is responsible for providing technical leadership and project management expertise in agricultural research to USAID and its Missions around the world, in the area of agricultural biotechnology and the application of molecular tools to plant and animal improvement. Dr. Heusing also serves as the AOR for the Biotechnology Potato Partnership	FY16-17
Jim Lorenzen The Bill and Melinda Gates Foundation	Jim Lorenzen is a Senior Program Officer in the Crops team of the Agriculture Development Division of the Bill & Melinda Gates Foundation, having joined in late 2012. His focus is on clonal crops (cassava, yam, sweet potato, banana/plantain), with special interests in crop improvement, plant health, and tools for seed systems. He worked in Nepal as Research Advisor to the National Potato Research Program (bilateral project of Swiss Dev. Cooperation) for 3 years before faculty positions at North Dakota State University (Potato Physiology, Germplasm Enhancement) and Idaho (Potato Molecular Biology) for 15 years. He has published on molecular mapping of pest and disease resistance in potato and banana, molecular characterization of potato virus Y, and potato and banana physiology/biotechnology.	FY16-21
Nicolas Champouret Ball Horticulture	Nicolas Champouret received his education at Wageningen University in the Netherlands and was employed at the Sainsbury Laboratory in Norwich, UK before becoming the Pathology Team Manager of Simplot where he worked extensively on transgenic potato. Currently Dr. Champouret is the Director, Molecular Marker Development and Bioengineering at Ball Horticulture based in the U.S.	FY16-21
Monica Garcia-Alonso Estel Consult Ltd.	Monica Garcia-Alonso has a degree in Biology from the University of Barcelona, specializing in zoology and entomology. She has a Masters in Insect Physiology and Ecology from the University of Barcelona and a PhD in Neurobiology from the University of Reading in the UK. Dr. Garcia-Alonso worked for Syngenta for 19 years as an environmental risk assessor and a regulatory affairs manager. Currently, she is the owner and principal consultant of Estel Consult. She has provided strategic guidance for global agricultural biotechnology projects, completed a wide range of regulatory submissions and conducted many environmental	FY16-21

	risk assessments for genetically modified crops, including submissions in the European Union.	
Dennis Halterman USDA-ARS	Dennis Halterman's work revolves around the molecular mechanisms of disease resistance in potato. Plant diseases are among the greatest deterrents to crop production worldwide. Diseases caused by fungi, viruses, bacteria, insects, and nematodes impact agronomic and horticultural crops, in addition to commercial and recreational forests. Major efforts have been devoted to understanding the mechanisms of genetic resistance and incorporating it into breeding programs to offset potential yield loss caused by pathogens. Dr. Halterman hopes that by understanding the molecular and genetic basis of resistance in plants, improvements can be made to the process of developing new crop varieties that require less pesticide application. A major focus of his work is exploring resistance to the oomycete pathogen <i>Phytophthora infestans</i> , which causes late blight on potato and tomato plants. In collaboration with other researchers, his lab also is working with potato hybrids with resistance to <i>Verticillium</i> wilt and others with resistance to <i>Alternariasolani</i> , causal agent of early blight of potato, and resistance to potato virus Y.	FY16-21
Achmed M. Fagi Consultant	Achmad Mudzakkir Fagi was appointed Consultant by Directorate General of Food Crops, Ministry of Agriculture, for Upland Agriculture Development in Pacitan (East Java), Wonogiri and Gunung Kidul (Central Java). 2010 –2011, Team Leader of FEATI (Farmer Empowerment through Agricultural Technology and Information), a World Bank funded project. 2012 –2014, Dr. Fagi was a Consultant of on Farm (National Bureau of Logistic) dealing with stock management, stabilization of rice prices and allocation of rice to the poor. He has received degrees in Agronomy and Philosophy	FY16-21
M Harun-ur-Rashid Consultant	Md. Rashid has 40 years of diversified service experience in agricultural research, development, technology transfer and teaching. Total service experience includes approximately 20 years active service in agricultural research, development and project management and 10 years of service as training & communication specialist. Dr. Rashid has over 20 years in service in donor funded projects and over 12 years of experience in university teaching as adjunct faculty. He was the Director General of Bangladesh Agricultural Research Institute (BARI) for two years; and the Executive Chairman of Bangladesh Agricultural Research Council (BARC) for one year. Additionally, Md. Rashid worked as the Bangladesh Team Leader in "Rice-Wheat Consortium for Indo-Gangetic Plains".	FY16-21

Paul Tanger USAID	Paul Tanger is a biologist by training with interdisciplinary experience across the fields of agriculture, genetics, bioinformatics, and alternative energy. Dr. Tanger completed his Ph.D. at Colorado State University, where his research examined the diversity of bioenergy traits in rice and sought to identify genes underlying these important traits. The goal of this research was to improve rice as a food crop, as well as a source of economical bioenergy from rice straw. Tanger served as USAID AOR for the Biotechnology Potato Partnership during FY18 and FY19.	FY18-19
Tracy Powell USAID	Tracy Powell serves as an agricultural research advisor for the US Agency for International Development, where she manages a portfolio of research programs in the areas of agricultural biotechnology and legume productivity. Currently based in Washington DC, she also previously worked at USAID's Mission to Ethiopia in Addis Ababa. Dr. Powell holds a Ph.D. in Plant Biology from the University of California Berkeley, where she researched molecular interactions between plants and their resident bacteria, and has additional research experience in molecular breeding, weed biology, and human immunology. Prior to joining USAID, she worked as a science writer for The Economist, The Berkeley Science Review, and Fred Hutchinson Cancer Research Institute. Tracy Powell served as USAID AOR for the Biotechnology Potato Partnership during FY20 and NCE.	FY20-21
Carolina Escobar-Ochoa Simplot Plant Sciences	Carolina Escobar-Ochoa studied at Michigan State University and is an Associate Pathology Scientist at Simplot Plant Sciences. Dr. Escobar-Ochoa's main interest and motivation as a plant pathologist is further deepening and exploring different interactions between microbio-pathogen-host providing an effective disease control and management, by the clear understanding of how they interact with each other. In addition to serve as an effective link between the research and growers.	FY19-21

ANNEX III – PROJECT AGREEMENTS

INSTITUTION	AGREEMENT TYPE
University of Minnesota	Sub-contract
University of Idaho	Sub-contract
J.R. Simplot Company	Sub-contract, IP, MTA
Bangladesh Agricultural Research Institute	Sub-contract, IP
Bangladesh Agricultural Research Council	MOU, Letter of Agreement (subcontract)
Indonesia Center for Agricultural Biotechnology Genetics Resources Research and Development	Exchange of Notes (sub-contract), IP
International Potato Center (CIP)	Collaborative, MTA
Venganza	Collaborative, MTA

ANNEX IV – PROJECT PARTNERS AND COLLABORATORS

ORGANIZATION	LOCATION
Alliance for Science	U.S.
Bangladesh Agricultural Research Institute	Bangladesh
Bangladesh Agricultural Research Council	Bangladesh
Bangladesh Agricultural University	Bangladesh
Cergentis	Netherlands
Centre for Alternative Dispute Resolutions, Regulation & Policy Analysis and Community Empowerment of Bogor University	Indonesia
Cornell University	U.S.
CropLife	Indonesia
Farming Future Bangladesh	Bangladesh
Geo Potato	U.S.
IndoBic	Indonesia
Indonesia Center for Agricultural Biotechnology Genetics Resources Research and Development	Indonesia
International Potato Center	Peru/Kenya
International Service for the Acquisition of Agribiotech Applications	Philippines
J.R. Simplot Company	U.S.
University of Idaho	U.S.
University of Minnesota	U.S.

ANNEX V – HICD KNOWLEDGE SURVEY

Questions for the Knowledge Survey

Technical (plant):

1. Do you have experience in handling of regulated plant material?
2. Have you had any experience in Potato tissue culture propagation?
3. What are (if any) your experiences in Potato seed production (greenhouse and field)?
4. Are you familiar with R-genes in potato for late blight resistance?
5. Do you have experience in plant transformation of potato?
6. Have you had any hands on experience in molecular characterization of transgenic events?
7. Do you have experience in experimental design of Confined Field Trials (CFTs)?
8. Do you have experience in experimental design of Greenhouse trials?

Pathology (pathogen):

1. What growth media do you use to isolate *Phytophthora infestans* from infected plant material?
2. What growth media do you use to culture *P. infestans* isolates and keep them for long term storage?
3. Do you ever prepare late blight inoculum for inoculating greenhouse or field trials. If so how do you prepare inoculum?
4. How do you rate late blight in greenhouse and field trials? e.g. do you look at incidence (number of infected plants per plot) and severity (diseased leaf area per plant or per plot?)
5. What are the main fungicides used to control late blight in Indonesia?
6. When collecting late blight infected plant material (e.g infected leaves) for disease surveys, what is your sampling strategy? i.e. how many infected plants would you sample from in each area?

Regulatory:

1. How familiar are you with National Biosafety requirements for research with GM plants (Lab, Greenhouse, Field)?
2. Do you follow Standard Operating Procedures (SOPs) for biosafety compliance when conducting research with GM plants (Lab, Greenhouse, Field)?

3. Do you have experience with record-keeping and reporting requirements for biosafety compliance when conducting research with GM plants?

Communication:

1. Have you had any exposure to biotechnology and biosafety communication for a GE crop or product?

Socioeconomics:

1. How familiar are you with the National policy requirements for socioeconomic considerations for GM crops?

2. Are you familiar with the National guidelines for socioeconomic assessments?

3. Do you have any knowledge of procedures for ensuring socioeconomic data quality and management?

ANNEX VI – HICD FY2017 INDONESIA WORKSHOP OVERVIEW

Training Workshop for Participants of the Legacy Potato and Feed the Future Biotechnology Potato Partnership Projects **Indonesia, January 23-27, 2017**

LEARNING OBJECTIVES:

Technical: Participants will know how to propagate plant material (plants and tubers) for greenhouse and confined field trials. They will understand the plant transformation methods and how the events are molecularly characterized. They also will understand the R-gene strategy.

Pathology: Participants will understand how to prepare media for isolation and culturing of *P. infestans*. - Pea agar (excellent for isolation), Rye A and Rye B (for culturing) and how to identify late blight lesions on potato leaves, stems and tubers. They also will understand the use of Pocket Diagnostics LFD test for rapid accurate identification and identifying sporangia under a dissecting microscope and isolation of *P. infestans* from leaves, stems and tubers and preparation of infected leaves for shipping to USA. Furthermore, participants will have a good understanding of how to maintain *P. infestans* isolates in culture.

Regulatory: Participants will understand why there is a need for biosafety compliance and what is required for importation/exportation and contained use (laboratory or greenhouse) of GM plant materials.

Participants will understand why there is a need for biosafety compliance and what is required for contained use (greenhouse), including data collection and analysis, of GM plant materials.

Pathology & Technical: Participants will understand how to prepare *P. infestans* inoculum for infection studies (greenhouse or field) and inoculate greenhouse plants for greenhouse infection studies. They will also have a clear understanding of Experimental design of greenhouse inoculation trials and how to rate foliar late blight symptoms in greenhouse studies.

List of Participants from Partner Countries

From Bangladesh:

1. Mosarraf Hossain Molla, Tissue Culture Lab
2. Mohammad Kamrul Islam, ABSP II
3. Md. Musfiqur Rahman, Pathologist
4. Ms. Fahmida Akhter, Biotechnologist
5. Shafiqul Islam, Breeder
6. Dr. Md. Jahangir Hossain, Country Coordinator

From Indonesia:

1. Dr. Muhammad Herman, Country Coordinator
2. Dr. A. Dinar Ambarwati (ICABIOGRAD)
3. Dr. Edy Listanto (ICABIOGRAD)
4. Mr. Kusmana (IVEGRI)
5. Ms. Ineu Sulastrini (IVEGRI)
6. Dr. Tri Joko Santoso (ICABIOGRAD)
7. Dr. Eny Ida Riyanti (ICABIOGRAD)
8. Dr. Toto Hadiarto (ICABIOGRAD)

Also attending:

1. Mr. Mohammed Shibly, USAID Bangladesh
2. Dr. Md. Shahidur Rahman Bhuiyan, USAID Bangladesh

From the US:

1. Dr. Dave Douches, MSU
2. Dr. John Medendorp, MSU
3. Dr. Karen Hokanson, MSU
4. Dr. Phil Wharton, MSU
5. Dr. Jane Payumo, MSU
6. Dr. Patrick Rüdelsheim, Persues

ANNEX VII – IN-COUNTRY CORE TECHNICAL TEAMS

Indonesia	Gender*	Area of Expertise	Organizational Affiliation
Dr. Alberta Dinar Ambarwati	Female	Principal Investigator	ICABIOGRAD
Dr. Edy Listanto	Male	Molecular Biology	ICABIOGRAD
Dr. Tri Joko Santoso	Male	Molecular Biology	ICABIOGRAD
Dr. Ineu Sulastrini	Female	Crop Pathology	IVEGRI
Kusmana Kusmana	Male	Potato Breeding	IVEGRI
Dr. Mosharraf Hossain Molla	Male	Principal Investigator	TCRC-BARI
Md Shafiqul Islam	Male	Technical Lead	TCRC-BARI
Fahmida Akhter	Female	Tissue Culture	TCRC-BARI
Md Musfiqur Rahman	Male	Pathology	TCRC-BARI
Dr. Yousuf Akond	Male	Principal Investigator	BARI Biotechnology Div
Dr. Mahmuda Kathun	Female	Trial Manager	BARI Biotechnology Div
Dr. Shyam Halder	Male	Trial Scientist	BARI Biotechnology Div
Dr. Most Mahbuba Begum	Female	Pathologist	TCRC-BARI

ANNEX VIII – EXTERNAL SCIENTIFIC PRESENTATIONS

Date	Topic	Event	Presenter
FY2016	Feed the Future Biotechnology Potato Partnership Project Overview	CIP's Asia Potato Program, International Potato Center	Karen Hokanson
FY2017	Update on Legacy Potato	14 th International Symposium on the Biosafety of Genetically Modified Organisms, Guadalajara, Mexico	Karen Hokanson
FY2017	Feed the Future Biotechnology Potato Partnership Project Overview and Update	14 th International Symposium on the Biosafety of Genetically Modified Organisms, Guadalajara, Mexico	Dave Douches
FY2018	Interdisciplinary Applied Research Approach for International Agricultural Development – Case Study of Bangladesh	James Madison College Symposium, Michigan State University, East Lansing, MI, U.S.	Hashini Galhena Dissayyanake
FY2018	Scope and Adequacy of Existing Risk Assessment and Regulatory Oversight for Synthetic Biology Preparing for COP14 – Issues to be Deliberated	6 th Annual South Asia Biosafety Conference, Dhaka, Bangladesh	Karen Hokanson
FY2018	Biosafety Risk Assessment and Regulation of Gene Edited Plants	6 th Annual South Asia Biosafety Conference, Dhaka, Bangladesh	Karen Hokanson
FY2018	Feed the Future Biotechnology Potato Partnership Project Overview and Update – Poster Session	6 th Annual South Asia Biosafety Conference, Dhaka, Bangladesh	Dave Douches
FY2018	Feed the Future Biotechnology Potato Partnership BARI activity– Poster Session	6 th Annual South Asia Biosafety Conference, Dhaka, Bangladesh	Mosharraf Hossain Molla
FY2018	Transgenic Approaches to Building Late Blight and Stress Tolerance into Commercial Potatoes	Plant Resilience Brown Bag Talk Michigan State University, East Lansing, MI, U.S.	Dave Douches
FY2018	Feed the Future Biotechnology Potato Partnership Project Overview and Update	North Central Potato Meeting, Chicago, IL, U.S.	Dave Douches
FY2018	Feed the Future Biotechnology Potato Partnership Project Overview and Update	Potato Association of America, Boise, ID, U.S.	Dave Douches

FY2018	Characterization of <i>Phytophthora infestans</i> isolates from Bangladesh	Potato Association of America, Boise, ID, U.S.	Phillip Wharton
FY2018	Development of Durable Resistance to late Blight In Indonesia	10 th World Potato Congress, Cusco, Peru	Phillip Wharton
FY2018	Rapid Detection and Characterization of <i>Phytophthora infestans</i> Isolates in the Field	International Congress of Plant Pathology, Boston, MA, U.S.	Phillip Wharton
FY2019	Feed the Future Biotechnology Potato Partnership Project Overview and Update – Poster Session	Potato Association of America, Boise, ID, U.S.	Dave Douches
FY2019	Feed the Future Biotechnology Potato Partnership Project Overview and Update	Michigan Winter Potato Conference, Grand Rapids, MI, U.S.	Dave Douches
FY2019	Feed the Future Biotechnology Potato Partnership Project Overview and Update	North Central Potato Meeting, Chicago, IL, U.S.	Dave Douches
FY2019	Data Elements of a GE Plant Application: Components of a Dossier Used to Fulfill ERA Requirements	ILSI ILSI RF CFTT Data Transportability Workshop,	Karen Hokanson
FY2019	Managing the Adaptation of the Potato Late Blight Pathogen to Disease Resistance Genes	15 th International Society for Biosafety Research Symposium, Tarragona, Spain	Phillip Wharton
FY2019	Development of a Durable Resistance to Late Blight in Indonesia	Potato Association Annual Meeting, Boise, ID, U.S.	Phillip Wharton
FY2019	Development of a Durable Resistance to Late Blight in Indonesia	Euroblight Workshop, York, U.K.	Phillip Wharton
FY2019	Public Sector GE Crop Development and Deployment	7 th Annual South Asia Biosafety Conference, Dhaka, Bangladesh	Karen Hokanson
FY2019	Feed the Future Biotechnology Potato Partnership Project Overview and Update	WorldTAP Agricultural Biotechnology, Biosafety, and Technology Transfer Short Course, Michigan State University, East Lansing, MI, U.S.	Dave Douches
FY2020	Potato Breeding in the 21 st Century	HRT/PSM Spring Seminar Series, Michigan State University, East Lansing, MI, U.S.	Dave Douches
FY2020	Breeding Process Framework: A Powerful Tool for Enhancing Desirable Traits in Potato	Advancing Plant Breeding and Crop Improvement for Meeting Future Challenges Symposium, Washington DC, U.S.	Dave Douches

FY2020	Potato Development and Variety Evaluations	2020 Winter Potato Conference, Mt. Pleasant, MI, U.S.	Dave Douches
FY2020	Feed the Future Biotechnology Potato Partnership Project Overview and Update	Potato Breeding and Genetics Technical Meeting, Chicago, IL, U.S.	Dave Douches
FY2020	Feed the Future Biotechnology Potato Partnership Project Overview and Update	Potato Expo, Las Vegas, NV, U.S.	Dave Douches
FY2020	Feed the Future Biotechnology Potato Partnership Project Overview and Update	World Potato Congress Webinar Series, Virtual	Dave Douches
FY2020	Genotypic Characterization of <i>Phytophthora infestans</i> isolates from Indonesia	Idaho Potato Conference, Boise, ID, U.S.	Phill Wharton
FY2021	Feed the Future Biotechnology Potato Partnership Project Overview and Update	North Central Regional Potato Breeding and Genetics Technical Meeting, Virtual	Dave Douches
FY2021	Feed the Future Biotechnology Potato Partnership Project Overview and Update	Potato Association of America 105 th Annual Meeting, Virtual	Dave Douches
FY2021	Feed the Future Biotechnology Potato Partnership Project Overview and Update	American Society of Horticultural Science Annual Conference, Virtual	Dave Douches
FY2021	Feed the Future Biotechnology Potato Partnership Project Overview and Update	Fireside Chat, Michigan State University, East Lansing, MI	Dave Douches
FY2021	Feed the Future Biotechnology Potato Partnership Project Overview and Update	Guatemala Ministry of Agriculture MSU Visit, Michigan State University, East Lansing, MI, U.S.	Dave Douches/Kelly Zarka

ANNEX IX – BOOK CHAPTERS AND PEER REVIEWED PUBLICATIONS

Wharton, P.; Dangi, S.; Begum, B.; Hokanson, K.; Douches, D., (expected 2022) “Genotypic and phenotypic characterization of <i>Phytophthora infestans</i> populations in Bangladesh, pending publication by Plant Pathology
Medendorp, J.; Payumo, J.; Weebaddee, C.; Zarka, K.; Hokanson, K.; Wharton, P.; Douches, D., (2021) “Case Study: A Roadmap for Developing Capacity in Plant Biotechnology Field Research” appears as book chapter in Current Topics in Agricultural Sciences Vol. 1 published by BP International
Zarka, K.; Hokanson, K.; Douches, D., (2021) “Molecular Characterization for Risk Assessment of a GM Late Blight Resistant Potato: An Unusual Case,” published by Transgenic Research https://link.springer.com/article/10.1007/s11248-021-00241-2
Ambarwati, D.; Santoso, T.J.; Kusmana; Herman, M., (2021) “Experience in Developing Genetically Engineered Potato Resistant to Late Blight Disease” appears as a book chapter in Genetically Modified Crops in Asia-Pacific from Research to Commercialization published by Commonwealth Scientific and Industrial Research Organization (CSIRO)
Dangi, S.; Wharton, P.; Ambarwati, A.; Santoso, T.; Kusmana; Sulastrini, I.; Medendorp, J.; Hokanson, K.; Douches, D., (2020) Genotypic and phenotypic characterization of <i>Phytophthora infestans</i> populations on Java, Indonesia , Plant Pathology https://doi.org/10.1111/ppa.13269
Ghislain, M.; Douches, D., (2019), The genes and genomes of the potato, appears as a book chapter in The Potato Crop: Its Agricultural, Nutritional and Social Contribution to Humankind published by Springer. https://link.springer.com/book/10.1007/978-3-030-28683-5
Schiek, B.; Hareau, G.; Baguma, Y.; Medakkar, A.; Douches, D.; Shotkoski, F; Ghislain, M., (2016) Demystification of GM crop costs: Releasing Late Blight Resistant Potato Varieties as Public Goods in Developing Countries , International Journal of Biotechnology https://www.inderscienceonline.com/doi/abs/10.1504/IJBT.2016.077942
Halterman, D.; Guenther, J.; Collinge, S; Butler, N.; Douches, D., (2015) Biotech Potatoes in the 21st Century: 20 years Since the First Biotech Potato , American Journal of Potato Research https://link.springer.com/article/10.1007/s12230-015-9485-1

Annex X – Communications Strategy



BIOTECHNOLOGY POTATO PARTNERSHIP COMMUNICATIONS STRATEGY



USAID
FROM THE AMERICAN PEOPLE



MICHIGAN STATE
UNIVERSITY

PROJECT OVERVIEW

The Feed the Future Biotechnology Potato Partnership is a five-year \$5.8 million cooperative agreement between Michigan State University (MSU) and USAID to introduce bio-engineered potato products in farmer- and consumer-preferred varieties into Bangladesh and Indonesia. The biotech potato products with three resistance genes (3 R-gene) from wild potato varieties offer broad-spectrum resistance to late blight (*Phytophthora infestans*), the most devastating potato disease in the world.

The partnership consists of agreements between USAID, MSU, The University of Minnesota (UMN), The University of Idaho (UI), The Bangladesh Agricultural Research Institute (BARI), the Indonesian Center for Agricultural Biotechnology Genetic Resources Research and Development (ICABIOGRAD), and the JR Simplot Company, to produce and steward the 3 R-gene potatoes for distribution to low-income smallholder farmers and for commercialization in Bangladesh and Indonesia.

Together with institutional partners, the project will work to: Meet regulatory requirements to ensure safety for human health and the environment. Develop and implement a communications strategy to inform the public and stakeholders of the benefits of the late blight potato. Develop institutional capacity in partner institutions and their respective governments. Work with the private sector in target countries to develop biosafety standard operating procedures. Develop and market quality seed to deliver the potatoes produced by the partnership to the farmers.

BPP contributes to the goals of

- reducing malnutrition and improving health;
- reducing the use of harmful pesticides;
- reducing pre- and post-harvest losses;
- improving the social and economic standing of women; and
- catalyzing economic growth

All these activities support and align with USAID's goal of increasing food security and resilience.

BANGLADESH

Bangladesh ranks 8th in global population with 167 million people living within a land mass approximately the size of the state of Nebraska. Projections show huge population growth by 2050 and coupled with shrinking land mass due to climate change, Bangladesh is seeking new ways to improve their agricultural systems and outputs.

GMO history Bangladesh has taken an aggressive position on the adoption of GE technology. BT brinjal received regulatory approval in 2014 and has seen rapid adoption with over 27,000 farmers (approx. 17%) planting the crop in 2018 up from 6,500 in 2017. BT cotton and Golden Rice are projected to soon be commercialized in country.

Public perception of GMO's: Unclear, although adoption rates and consumption of BT brinjal are increasing exponentially, they still represent a small percentage of the overall brinjal market. Anti GM activism is moderate. Several anti-GM activists regularly are published in daily news sources and a few protests occur from time to time. Last consumer survey on GMO's was conducted in 2003. More information is needed to get a good pulse on GMO attitudes. Consumers are highly influenced by religious and government leaders and targeting an informational campaign to these groups would be beneficial.

INDONESIA

Indonesia ranks 4th in global population with 268 million people. The country is comprised of over 18,000 islands across a region of immense volcanic activity. The majority of Indonesians live on just five of the islands and farming land is often steep and difficult to cultivate. Due to climate, Indonesia potato farmers are faced with intense late blight disease, often devastating their entire crop.

GMO history: Indonesia is 4th largest importer of US Soybeans, of which over 90% of the crops are GE. Indonesia has been conducting research on GM technology since the early 1990's. Despite a comprehensive GE risk assessment framework, governmental approvals remain on hold due to added requirements by the Ministry of Agriculture. However, drought tolerant sugarcane has recently been approved for commercialization in country.

Public perception of GMO's: Unclear, although most Indonesians consume GE soybeans imported from US. Anti GM activism is relatively quiet. The last consumer perception survey on GMO's was conducted in 2003. More information on how the public perceive GE technology could be critical in crafting key messages.

COMMUNICATIONS STRATEGY

Effective and efficient communication of the project's objectives, goals, and outcomes is critical to the overall success of the program. BPP communication efforts focus on both internal and external strategies.

Internal communications will be targeted to two groups; the core management team and the collaborative project network. The communications strategy for the core management team is to build and maintain a strong internal connection to ensure a free flow of information to meet project goals on time, keep the team informed of external biotechnology news and events and to create "best messages" for the team when communicating outside the project. Tools used to implement this strategy will include regularly scheduled management meetings (via Zoom or similar platform), face-to-face meetings, WhatsApp groups, shared files – Teams, Smartsheets, weekly team email updates and quarterly reports.

The collaborative project network is comprised of the Technical Advisory Board (TAB), partner organizations (BARI, ICABIOGRAD, USAID missions) along with innovative global institutions in research and development (ie - International Potato Centre – CIP) and outreach (ie – ISAAA, Alliance for Science) that the project has built formal and informal relationships with. The communications strategy for this group is to build an interactive exchange of information to leverage specialized capacities to further the overall goals of the project. Tools used to implement this strategy include virtual meetings (via Zoom or similar platform), WhatsApp groups, quarterly e-newsletters and reports. BPP will also conduct quarterly virtual meetings with the TAB, with a face-to-face meeting to be held every other year.

The external communications strategy will be focused on proactive engagements that explain the benefits of genetic engineering in clear, concise, easy to understand terms and language using transparent science and fact-based messages that meet target audiences' needs and values. The project will partner with biotechnology advocacy groups, organizations, projects and universities globally to further cohesive messaging strategies and efforts. BPP will passively monitor anti-GMO activists and only engage on a crisis basis if deemed necessary by project leadership.

Communications tools to be used to reach our external audience include website, social media platforms Twitter and Facebook, e-newsletters, videos and workshops/events. Information and educational printed leave behind materials to support non-tangible tools. Success stories distributed through earned media in industry news, Feed the Future/USAID publications, and mainstream media.

Both internal and external communication strategies will be reviewed and evaluated regularly to ensure they are meeting desired outcomes and adjusted as necessary.

MESSAGING

The Biotechnology Potato Partnership communication message has been crafted to advance the strategy as outlined above.

Message: The combined challenges of increased world population and global climate change make it critical that we develop and utilize the best possible combinations of technologies to feed future generations. Genetic engineering is one technology that can increase agricultural productivity and the economic standing of smallholder farmers in developing countries while reducing inputs and environmental impacts. The genetically modified late blight resistant potato has been scientifically proven to be safe for humans and for the environment.

In order to validate that the message resonates with the audience, the project is planning to conduct consumer perception studies in both Bangladesh and Indonesia. These studies will examine the current attitudes of key stakeholder groups as they relate to GM technology. The messages can then be further refined to create message matrices for each target group.

TARGET AUDIENCE

As mentioned the project will focus on both internal and external target audiences. The internal audience has been defined as the core management team and the collaborative project network (see communications strategy above for detailed summary).

The external primary target audience is global and includes many stakeholder groups. These groups have been further identified as either Influencers or Users. Influencers hold a certain degree of power over GMO crop acceptance and use their influence to sway user behavior and beliefs. Users represent the end consumer of the potato. Influencers are also considered users.

Influencers include the following groups in both Indonesia and Bangladesh: government officials and regulators; scientists and researchers; agricultural extension officers, farmers, seed producers, chemical companies; potato brokers and retailers; religious figures; and media representatives.

With USAID as the primary funder of the project, BPP also recognizes US citizens as a secondary target audience.

TIMELINE

The communication implementation strategy is tied to the project development timetable. Three phases have been identified:

- Phase One - General information on the technology - definition, safety, nutrition, socio-economic, environmental advantages. Goal: Create a positive environment to begin the conversation on the benefits of GMO technology targeted to influencers.
Project Years 1-5

- Phase Two - Conduct consumer perception study in Bangladesh and Indonesia. Goal: Promote transparency to build trust with fact-based messaging targeted at influencers and users based on real data gleaned from current perceptions.
Years 4-5
- Product release, success stories, benefits of new technology. Goal: Adoption and acceptance of the late blight resistant potato by influencers and user.
Year 5+

CHALLENGES

The project faces several communications challenges. These include:

- Anti GM Activism – Promotion of misinformation and fear-based messaging is a standard tactic of anti-gm activists.
- Unknown Consumer Perception of GM Technology – Execution of perception studies are critical to understanding what messages will resonate with the people of Bangladesh and Indonesia.
- Diverse Global Target Audiences with Socio Economic Disparity – Rural and urban differences are vast and availability of information is not uniform
- Multiple Languages – Need to ensure messages are translated properly and effectively.
- Low Literate Learners – Creative and varied methods for translating our method must be thought out for all levels of learners.
- Potential Political Instability – The political landscape in both countries, although stable at this time can be a factor.

OPPORTUNITIES

Several opportunities exist to leverage communication strategy for the project.

- Collaboration – Several key biotechnology advocacy groups have emerged to promote the education and acceptance of biotech crops globally. The project will collaborate with this groups as often as possible.
- Success of other GE Crops – The project can build off of existing GMO crops successes.
- Social Media – Social media can be a powerful tool in reaching target audiences and building technology influencers.
- Solid Science – GMO technology has over 20 years of fact-based science with proven results.

ANNEX XI – ARTICLES, NEWSLETTERS, PRESENTATIONS, VIDEOS FOR STAKEHOLDER ENGAGEMENT

Fierro, J.; Douches, D., (2021), Biotechnology Media Event led by the USAID Bangladesh Mission. Virtual. Presentation
Douches, D; Fierro, J., (2021), How One Plant Breeder Innovates to tackle Potato's Biggest Challenge . The Chicago Council on Global Affairs, Global Food for Thought Blog. Article https://www.thechicagocouncil.org/commentary-and-analysis/blogs/how-one-plant-breeder-innovates-tackle-potatos-biggest-challenge
Fierro, J., (2021). Feed the Future Biotetchnology Potato Partnership, Newsletter 2021 . Constant Contact. Electronic Publication Fierro, J., (2019). Feed the Future Biotetchnology Potato Partnership, Newsletter 2019 Vol.4 Constant Contact. Electronic Publication https://myemail.constantcontact.com/Quarterly-Update-Volume-Four-2019.html?soid=1130045626052&aid=nK6pr7qHqgM
Fierro, J., (2020), Researchers Map Late Blight Strains In Potato on Java, Indonesia . Potato Pro. Article https://www.potatopro.com/news/2020/researchers-map-late-blight-strains-potato-java-indonesia?utm_source=PotatoPro&utm_campaign=f9c5399fa2-GPS-WEEKLY-US-AG&utm_medium=email&utm_term=0_af560c7189-f9c5399fa2-297157961
Halterman, D; Richael, C.; Douches, D., (2020), Biotech Potatoes Can Bring Improved Performance, Quality to Global Markets . Spudman. Article https://spudman.com/article/biotech-potatoes-improved-performance-quality-global-markets/
Fierro, J., (2020), MSU Researcher Reflects on First Earth Day Celebration; “It Inspired Me to Dedicate My Career to Potato Research . CANR Newsletter. https://www.canr.msu.edu/news/msu-researcher-reflects-on-first-earth-day-celebration-it-inspired-me-to-dedicate-my-career-to-potato-research
Fierro, J., (2020). Feed the Future Biotetchnology Potato Partnership, Newsletter 2020 . Constant Contact. Electronic Publication Constant Contact. Electronic Publication https://myemail.constantcontact.com/Quarterly-Update-Volume-Four-2019.html?soid=1130045626052&aid=nK6pr7qHqgM
Fierro, J.; Cole, D.; Hossain, A., (2019) Feed the Future Biotechnology Potato Partnership . YouTube. Video https://www.youtube.com/watch?v=2mxkoX_UTEg
Fierro, J., (2019). Feed the Future Biotetchnology Potato Partnership, Newsletter 2019 Vol.4 Constant Contact. Electronic Publication https://myemail.constantcontact.com/Quarterly-Update-Volume-Four-2019.html?soid=1130045626052&aid=nK6pr7qHqgM
Fierro, J., (2019). USAID Feed the Future Biotechnology Potato Partnership and GE Technology Overview. East Lansing, MI: World Food Prize Youth Institute Day. Presentation
Fierro, J., (2019). Feed the Future Biotetchnology Potato Partnership, Newsletter 2019 Vol.3 Constant Contact. Electronic Publication https://myemail.constantcontact.com/Quarterly-Update-Volume-Three-2019.html?soid=1130045626052&aid=bxcKVGihYPo
Fierro, J., (2019). In The Field with Pathologist Phillip Wharton . Feed the Future Biotechnology Potato Partnership Quarterly News. Article https://www.canr.msu.edu/news/in-the-field-pathologist-phillip-wharton-is-on-the-hunt
Fierro, J., (2019). Feed the Future Biotetchnology Potato Partnership, Newsletter 2019 Vol.2 Constant Contact. Electronic Publication https://myemail.constantcontact.com/Quarterly-Update-Volume-Two-2019.html?soid=1130045626052&aid=GjRvILN53zY
Fierro, J., (2019). USAID Feed the Future Biotechnology Potato Partnership Project Communication Strategy. Ithaca, NY: Cornell Alliance for Science Global Leadership Fellows Communications Week. Presentation
Fierro, J., (2019). Feed the Future Biotetchnology Potato Partnership, Newsletter 2019 Vol.1 Constant Contact. Electronic Publication https://myemail.constantcontact.com/Quarterly-Update-Volume-One-2019.html?soid=1130045626052&aid=Hh9yH_rID3w
Fierro, J., (2018), Feed the Future Biotechnology Potato Partnership Launches 3R-Gene Late

Blight Resistant Potato in Bangladesh. South Biosafety Program Newsletter, pp. 1-2. Article
Fierro, J., (2018). Feed the Future Biotetchnology Potato Partnership, Newsletter 2018 Vol.4 Constant Contact. Electronic Publication https://myemail.constantcontact.com/Quarterly-Update-Volume-Four--2018.html?soid=1130045626052&aid=sjkiSPqEEVY
Fierro, J., (2018), Introduction to the Importance of Communicating your Science. Dhaka, Bangladesh: 6th Annual South Asia Biosafety Conference. Presentation
Hossain, A., (2018)., Using Social Media, Why it's Important, Best Practices and How to Begin. Dhaka, Bangladesh: 6th Annual South Asia Biosafety Conference. Presentation
Fierro, J., (2018). Feed the Future Biotetchnology Potato Partnership, Newsletter 2018 Vol.3 Constant Contact. Electronic Publication https://myemail.constantcontact.com/Quarterly-Update.html?soid=1130045626052&aid=DOawAcA0IyY
Fierro, J., (2018). Biotech Breeding Looks to Knock Out Late Blight . Global Potato News Magazine. Article. https://www.potatonewstoday.com/2018/11/20/biotech-potato-breeding-project-looks-to-knock-out-late-blight/
Fierro, J., (2018). Feed the Future Biotetchnology Potato Partnership, Newsletter 2018 Vol.2 Constant Contact. Electronic Publication https://myemail.constantcontact.com/Spring-2018-Quarterly-Update.html?soid=1130045626052&aid=H3SweWXAM4
Fierro, J., (2018). Feed the Future Biotechnology Potato Partnership Launches 3R-Gene Late Blight Resistant Potato in Bangladesh . South Asia Biosafety Newsletter. Article https://m.mdgottwald.com/wp-content/uploads/2021/01/ILSIRF_SABP_01_January_2018.pdf
Fierro, J., (2018). Feed the Future Biotetchnology Potato Partnership, Newsletter 2018 Vol.1 Constant Contact. Electronic Publication https://myemail.constantcontact.com/Winter-2018-Quarterly-Update.html?soid=1130045626052&aid=Sy9oEoN8yz0
Lashbrook, B., (2017). Biotech in Indonesia and Bangladesh . Michigan State University, College of Agriculture and Natural Resources, In the Field. Article https://www.canr.msu.edu/news/biotech_in_indonesia_and_bangladesh
Fierro, J., (2017). Feed the Future Biotetchnology Potato Partnership, Newsletter 2017 Vol.1 Newsletter. Electronic Publication https://www.canr.msu.edu/biotechpp/publications/ftf%20newsletter%2010.15%20page_compressed.pdf
Ghislan, M.; Douches, D.; Fierro, J.; Zarka, K., (2017) Field Test of Biotech Potato Shows Impressive Control of Late Blight Disease . International Potato Center News. Blog https://cipotato.org/press_room/blogs/field-test-biotech-potato-shows-impressive-control-late-blight-disease/

ANNEX XII – MONITORING, EVALUATION AND LEARNING (MEL) PLAN

MONITORING, EVALUATION AND LEARNING (MEL) PLAN FEED THE FUTURE BIOTECHNOLOGY POTATO PARTNERSHIP PROGRAM 2016-2020

Purpose

This document prepared by the project's M&E Lead (Dr. Jane G. Payumo) serves as a guide to monitoring, evaluation and learning within the FTF Biotech Potato Partnership Program. The project management team and in-country partners apply the tools provided in this plan.

Project Summary

The Feed the Future Biotechnology Potato Partnership (FtFBPP) is a five-year, \$5.8 million multi-institution cooperative agreement with USAID to introduce bio-engineered potato products in farmer- and consumer-preferred varieties into Indonesia and Bangladesh. The biotech potato products (with single or stacked resistance genes) offer broad-spectrum resistance to late blight (*Phytophthora infestans*), the most devastating potato disease in the world, and were developed through gene insertion and gene silencing approaches.

FtFBPP involves a collaborative partnership between USAID, Michigan State University (MSU), the University of Minnesota (UMN), the University of Idaho (U of I), the Bangladesh Agricultural Research Institute (BARI), the Indonesian Center for Agricultural Biotechnology Genetic Resources Research and Development (ICABIOGRAD), the Indonesia Vegetable Research Institute (MEGRI), the International Potato Center (CIP), and the J.R. Simplot Company (JRSC). FtFBPP and partner institutions will steward these biotech potato products for distribution to low-income farmers and commercialization. FtFBPP provides strategic human and institutional capacity building support (research, development and outreach) to in-country partners to support access to, technology transfer, and sustainable use of biotech potato products.

Project Goals

The Biotech Potato Partnership aims to: 1) develop and implement appropriate tools and processes for regulatory and stewardship compliance; 2) develop and implement a communications strategy to inform the public and stakeholders of the benefits of the late blight resistant (LBR) potato; 3) develop institutional capacity in biotechnology, biosafety and product stewardship; and 4) work with the private sector in the target countries to develop biosafety standard operating procedures and commercialize genetically modified (GM) potato seeds produced through this project.

The environmental impact, gender balance contribution and socio-economic impact of the GM products produced through this project will be carefully monitored and assessed. Overall, the project will contribute to the goals of: 1) reducing malnutrition and improving health; 2) reducing the use of harmful pesticides; 3) reducing pre- and post-harvest losses; 4) improving the social and economic standing of women; and 5) catalyzing economic growth.

Technologies

1. 3 R-gene LBR potato by Simplot for transformation into at most two farmer-preferred potato varieties for field testing in Bangladesh and Indonesia

2. Single R-gene LBR potato by Cornell's Agricultural Biotechnology Support Project (ABSP) II project (now relabeled as *Legacy Potato**) including SP951 (Katahdin transformed with the potato RB gene), D951 (hybrid clone of SP951 and Diamant) and six hybrid clones from ICABIO GRAD (two clones from Atlanticx Katahdin SP951 and four clones from Granola x Katahdin SP951)
3. 3 R-gene LBR potato by the International Potato Center (CIP), Nairobi, Kenya, including three transformed varieties (Desiree, Victoria/Asante variety, and Tigon) with a three gene stack consisting of the RB, the Rpi-blb2, and the Rpi-vnt1 resistance genes
4. Vengarza RNAi potato by Vengarza Inc. in collaboration with Cornell University including an RNAi-modified Katahdin variety and SP951 (Katahdin variety with the RB gene)

* *Legacy potato* refers to Katahdin SP951 as well as its hybrid clones.

Project Team

Table 1 presents the professionals and internationally-engaged experts from the U.S., Bangladesh, Indonesia and other countries that comprise the FFBPP project team. Together, they have identified the project goals and strategically prioritized scheduled activities.

Table 1. FFBPP project personnel.

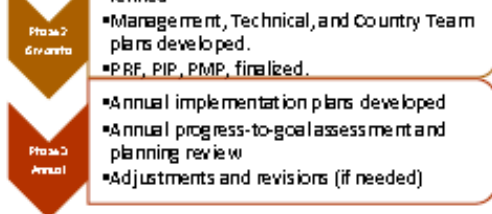
ROLE	NAME OF FFBPP PERSONNEL	AFFILIATION
Project Director and Technical Team Lead	Dr. David Douches	Michigan State University
Project Assistant to the Director	Ms. Kelly Zarka	Michigan State University
Technical Assistant to the Director	Mr. Joe Coombs	Michigan State University
Project Manager	Dr. John Medendorp	Michigan State University
Project Assistant to the Manager	Ms. Barbara Bird	Michigan State University
Regulatory Lead	Dr. Karen Hokanson	University of Minnesota
Regulatory consultant	Dr. Peter Raymond	Program for Biosafety Systems
Regulatory consultant	Dr. Patrick Rudelsheim	Perseus, BVBA
Regulatory consultant	Dr. Vanessa Cook	Cook-Marten Consulting, LLC
Regulatory consultant	Dr. Natalia Bagdanova	Biotechnology Regulatory Solutions, Inc.
Regulatory consultant	Dr. Monica Garcia Alonso	Estel Consult, Ltd.
Regulatory consultant	Dr. Mike Wach	Michael Wach Consulting
Regulatory consultant	Dr. Bill Pilacinski	WP Consulting, LLC
Monitoring and Evaluation (M&E) Lead	Dr. Jane Payumo	Michigan State University
Financial Lead	Mrs. Michelle McLain	Michigan State University
HICD Lead	Dr. Cholani Weebaddee	Michigan State University
Socio-Economic Lead	Dr. Hashini Galhena	Michigan State University
IP and Partnerships Lead	Dr. Karim Maredia	Michigan State University
Communications Lead	Ms. Janet Fierro	Michigan State University
Project Pathologist	Dr. Phil Wharton	University of Idaho

In-Country Coordinator (Indonesia)	Dr. Muhammad Herman	Formerly from ICABIOGRAD
In-Country Project Director (Bangladesh)	Dr. Md. Jahangir Hossain	Formerly from BARI
AOR and Technical Advisory Board (ex-officio member)	Dr. Joe Huesing	USAID, Washington, DC
Technical Advisory Board	Dr. Jim Lorenzen	The Bill & Melinda Gates Foundation
	Dr. Nicolas Champouret	Simplat
	Dr. Dennis Halterman	USDA-ARS Vegetable Crops Research Unit
	Achmad M. Fagi	Ministry of Research and High Education - Research and Development Center for Food Crops, Indonesia
	M Harun-ur- Rashid	Formerly from Bangladesh Agricultural Research Council and BARI

Logical Framework and Progress Made

The project uses causal logic framework (see Table 1) to plan, monitor, and evaluate the Partnership's performance by listing specific outputs and outcomes for each of the project's

components and by measuring progress through quantifiable indicators under each of the project objectives. This process occurs in a three-phase Performance Monitoring Plan (see Figure 1).



Planning: Institutional capacity building, product development, and regulatory action at multiple institutions requires a carefully designed, multi-level planning, monitoring, and evaluation approach designed with our technical teams and in-country counterparts.

The management team uses USAID's causal logic planning processes to generate measurable project objectives. Upon project inception and

Figure 1: Three-phase Performance Monitoring Plan for USAID Biotechnology Potato Partnership

during Phase 1 (first three months), MSU led an in-country baseline needs assessment and consultation for each of the

main project components. Work plans were developed from the baseline assessment. Also during Phase 1, a project plan was developed and circulated among all project participants for comment and suggestions. Once project participants have agreed to a project plan, during the Phase 2 (six months) MSU Team worked closely with the technical teams and country partners to define the project outputs, outcomes, and indicators as well as refine the management, technical, and country team plans. By the end of Phase 2 the project results framework (PRF), project management plan (PMP), and the project implementation plan (PIP) were finalized. Building on the foundation of the ABSP II project and the baseline assessment, plans were also developed for the management team,

these reviews and help the Project Team identifies which activities and corresponding indicators were met, completed, on track and or delayed (Figure 2).

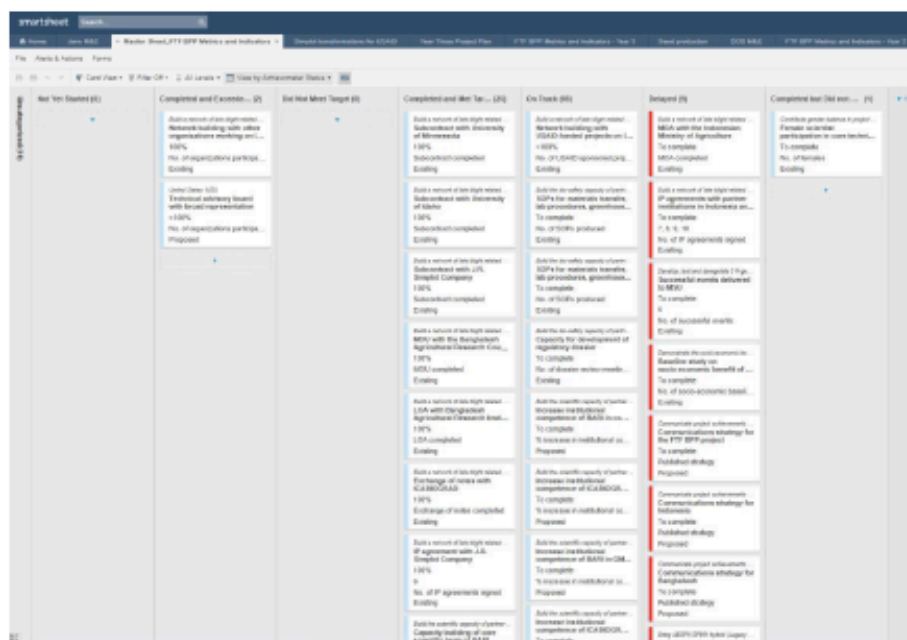


Figure 2: Metrics dashboard for the biotech potato project.

Two methods for project evaluation are being employed: output measures (process evaluation) and outcome evaluation to evaluate the program's activities and impact. These methods will help the project address the following evaluation questions: 1) process – Are the activities being implemented as planned? and 2) outcome – Is the project achieving its objectives that support the goals? Through output measures, the outputs of the project's activities (e.g. how many technologies have been deregulated and commercialized) will be quantified. Outcome evaluation, on the other hand, will be used to determine if the program is able to achieve desired changes in attitudes, behavior, knowledge (e.g. in tissue culture competency for in-country scientists in Bangladesh and Indonesia) because of the project intervention.

Evaluation instruments (pre-, post and post-follow up) are also designed to measure short- and medium-term outcome of specific intervention (e.g. training workshops, seminars and events). Each of these HICD activities has clear, measurable goals and feedback on training facilitation, which are all collected and evaluated. Information gathered during monitoring and evaluation are useful for

review and revise existing processes to enable a constant improvement in the implementation of project's activities.

Reporting, Communication and Feedback Loops: For each project component, in order to ensure implementation of activities and success in meeting objectives, and to complement the established protocols for USAID project reporting through FTFMS reporting system, the M&E Lead develops a reporting regime (quarterly) by which all progress in meeting outcomes and outputs are collected from all project team members. Figure 3 provides a screenshot of reporting tool developed in Qualtrics https://msu.qualtrics.com/jfe/form/SV_a63hVXcc826me1 for the project team. This tool gathers qualitative and quantitative description of success of each objective and activity of the project. All quarterly reports are used to generate the annual technical reports of the project. Through the reporting process, the M&E Lead identifies where further assistance is needed, suggest improvements to the processes, modify indicators, and identify new goals as needed.

The team uses Qualtrics and these reports were consolidated by the M&E Lead starting May 2017 and serve as important reference for the preparation of semi-annual, annual reports and FTFMS indicators reporting required by USAID.

FTFMS indicators: At present, the project through the M&E Lead, reports progress and data for six FTFMS indicators:

- 1) EG.3-1: (4.5.2-13) Number of households benefiting directly from USG interventions
- 2) EG.3.2-1: (4.5.2-7) Number of individuals who have received USG-supported short-term agricultural sector productivity or food security training
- 3) EG.3.2-4: (4.5.2-11) Number of for-profit private enterprises, producers organizations, water users associations, women's groups, trade and business associations, and community based organizations (CBOs) receiving USG food security related organizational development assistance
- 4) EG.3.2-5: (4.5.2-12) Number of public-private partnerships formed as a result of USG assistance
- 5) EG.3.2-7: (4.5.2-39) Number of technologies or management practices under research, under field testing, or made available for transfer as a result of USG assistance
- 6) EG.3.2-17: (4.5.2-5) Number of farmers and others who have applied improved technologies or management practices with USG assistance

Every three months, the Partnership Director also convenes a virtual Project Team meeting that includes the Management Team (Partnership Director, Regulatory Affairs Manager, Financial Manager, Project Manager), the Technical Team leads, and the in-country Directors. Quarterly reports are circulated prior to the meeting and serves as the basis of the quarterly project evaluation. These meetings are conducted to: 1) evaluate progress to date measured against project indicators, 2) discuss problems and challenges being faced by the project, 3) use lessons learned to adjust, refine, and improve project plans to ensure that project goals are met in a timely and effective manner. In addition, on a weekly basis the Management Team meets in virtual communication with the technical teams to review product development progress.

Data Management and Knowledge Sharing

The project generates quantitative and qualitative data. The M&E Lead collects these data from the Project Technical Team, synthesize findings, and prepare reports for USAID. The M&E Lead saves quantitative and qualitative data in Smartsheet for analysis and use data visualization tools to represent data graphically and to better communicate project results. The M&E Lead presents various analyses of these data as required in tables, figures, and graphs using stable format such as .jpg or .tiff. These data formats are well-established and do not suffer representative limitations for any produced.

Data are saved in Project Team computers (e.g. molecular data collected by the Technical team). However, all these data are collected by the M&E Lead as needed for reporting; and saved and backed-up and archived in MSU's Spartan Drive. Project files are also saved in MSU SharePoint. These approaches will allow us to store the data for a longer-term and avoid data loss. As an institutional policy, Michigan State University requires that primary data be retained for three years after publication. The project intends to store the data after this period (e.g. 10 years or more for future use). We will make sure we re-evaluate the utility of our data for longer period.


As part of the reporting requirements, the project submits collected data, results, and progress reports to USAID. The Communications Lead also shares quarterly and annual technical reports submitted to USAID with all program team and internal program participants. The Communications Lead helps popularized these reports for sharing with external audiences. The Communications Lead also publicly share preliminary program results and success stories through the project's website, USAID, country-mission, and bureaus' websites, as well as Feed the Future, scientific, and non-scientific meetings, and events.

All data, analytical methods, and findings generated by the project are being packaged and shared freely available to the wider scientific community and have no restrictions. The Project Team are not aware of any reasons that might prohibit the access, sharing and reuse of the data that will be generated from these activities and data that are funded by USAID. Preliminary project results are publicly shared through the project's website, workshops and conference presentations and soon in peer-reviewed journal publications. Data and results can be re-used by other parties with appropriate acknowledgement on the source. There is no agreement with any other institution for a grace period of release of data or Right of First Use for all data collected and analyzed through this project.

When applicable, the project ensure that all data and intellectual works produced by the project are shared to USAID's Development Data Library (DDL) <https://www.usaid.gov/data> as required by the USAID's new open data policy. The M&E Lead will ensure the dataset is complete and work with USAID to ensure that research data are deposited also in Ag Data Commons. The project will likewise use an open source research data repository software (e.g. Dataverse dataverse.org, Open Science Framework or Mendeley: <https://www.mendeley.com/>) or other discipline-based repositories, if available, to help increase the project's research outputs' visibility and not only make it more discoverable by the scientific and research community but also encourage credit, attribution, and increased citation.

The Project Director (Dr. David Douches) has the overall responsibility for implementing the project's data management plan and knowledge sharing activities. The M&E Lead packages all data, analytical methods, and findings and works with the Communications Lead to disseminate it based on the information needs and requirements of the target audience, including format (oral, written or web/electronic), and timeline. All dissemination efforts are guided by USAID's branding and marking guidelines.

ANNEX XIII – FINANCIAL DOCUMENTS


Federal Financial Report (Follow form instructions)				OMB Approval Number: 4040-0014 Expiration Date: 03/23/2022	
1. Federal Agency and Organizational Element to Which Report is Submitted US Agency for Intl Development			2. Federal Grant or Other Identifying Number Assigned by Federal Agency (To report multiple grants, use FFR Attachment) AID-OAA-A-15-00056		
3. Recipient Organization (Name and complete address including Zip code) Recipient Organization Name: Michigan State University Street 1: Contract & Grant Administration Street 2: 426 Auditorium Road, Room 2 City: East Lansing County: State: MI Province: USA: United States ZIP Postal Code: 48824-1046					
4a. DUNS Number 155247145		4b. EIN 38-6005934		5. Recipient Account Number or Identifying Number (To report multiple grants, use FFR Attachment) RC105463	
6. Report Type a. Quarterly b. Semi-Annual c. Annual X. Final		7. Basis of Accounting X. Cash a. Accrual		8. Reporting Period From: 9/30/2015 To: 9/30/2021 9. Reporting Period End Date: 9/30/2021	
10. Transactions (Use lines a-d for single grant reporting) Federal Cash (To report multiple grants, also use FFR Attachment)				Cumulative	
a. Cash Receipts				\$ 6,473,859.50	
b. Cash Disbursements				\$ 6,473,859.50	
c. Cash on Hand (line a minus b)				\$ -	
(Use lines d-f for single grant reporting) Federal Expenditures and Unobligated Balance					
d. Total Federal funds authorized				\$ 6,473,859.50	
e. Federal share of expenditures				\$ 6,473,859.50	
f. Federal share of unfunded obligations				\$ -	
g. Total Federal share (sum of lines e and f)				\$ 6,473,859.50	
h. Unobligated balance of Federal funds (line d minus g)				\$ -	
i. Recipient share					
i. Total recipient share requested				\$ 137,221.00	
j. Recipient share of expenditures				\$ 137,221.00	
k. Remaining recipient share to be provided (line i minus j)				\$ -	
Program Income					
l. Total Federal program income earned				\$ -	
m. Program income expended in accordance with the deduction alternative				\$ -	
n. Program income expended in accordance with the addition alternative				\$ -	
o. Unexpended program income (line l minus line m or line n)				\$ -	
11. Indirect Expenses					
a. Type	b. Rate	c. Period From	Period To	d. Base	e. Amount Charged
Pre-determined	20.00%	9/30/2015	9/30/2021	\$3,236,929.75	\$647,385.95
g. Totals:				\$3,236,929.75	\$647,385.95
12. Remarks: Attach any explanations deemed necessary or information required by Federal sponsoring agency in compliance with governing legislation.					
13. Certification: By signing this report, I certify that this true, complete, and accurate to the best of my knowledge and belief; that this report is true, complete, and accurate; and that expenditures, disbursements and cash receipts are for the purpose and objectives set forth in the terms and conditions of the Federal award. I am aware that any false, fictitious, or fraudulent information, or the omission of any material fact, may subject me to criminal, civil, or administrative penalties for fraud, false statements, false claims or otherwise. (U.S. Code, Title 18, Section 1001 and Title 31, Sections 3729-3733 and 3801-3812)					
a. Name and Title of Authorized Certifying Official Print: First Name: Jeffrey Middle Name: Last Name: Sanghaal Title: Contract & Grant Administrator					
b. Signature of Authorized Certifying Official 			c. Telephone (Area code, number and extension) 517-334-4240		
d. Email Address contractmgr@overseas.edu			e. Date Report Submitted: 12/19/2021 f. Agency use only		

Standard Form 425

Paperwork Burden Statement
 According to the Paperwork Reduction Act, as amended, no persons are required to respond to a collection of information unless it displays a valid OMB Control Number. The valid OMB control number for this information collection is 4040-0014. Public reporting burden for this collection of information is estimated to average 1 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: US Department of Health & Human Services, OHSO OIPRA, 200 Independence Ave., SW, Suite 205C, Washington DC 20201. Attention: PRA Regulatory Clearance Office

TANGIBLE PERSONAL PROPERTY REPORT SF- 428

OMB Number: 4040-0018
Expiration Date: 6/30/2020


1. Federal Agency and Organizational Element to Which Report is Submitted US Agency for Intl Development		
2. Federal Grant or Other Identifying Number Assigned by Federal Agency AID-0AA-A-15-00056	3a. UEI A288K928289	3b. EIN 138-6005924A1
4. Recipient Organization (Name and complete address including zip code) Recipient Organization Name: Michigan State University Street1: 426 Auditorium Road, Room 2 Street2: City: East Lansing County: State: MI: Michigan Province: Country: USA: UNITED STATES ZIP / Postal Code: 48824-2600		
5. Recipient Account or Identifying Number AC105463	6. Attachment (Check applicable) <input type="checkbox"/> Annual Report (SF-428-A) <input checked="" type="checkbox"/> Final Award Closeout Report (SF-428-B) <input type="checkbox"/> Disposition Report Request (SF-428-C)	7. Supplemental Sheet <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
8. Comments <div><input type="text"/> <input type="button" value="Add Attachment"/> <input type="button" value="Delete Attachment"/> <input type="button" value="View Attachment"/></div>		
9a. Typed or Printed Name and Title of Authorized Certifying Official Prefix: First Name: Jeffrey Middle Name: Last Name: Banghaet Suffix: Title: Contract and Grant Administrator		
9b. Signature of Authorized Certifying Official 		
9c. Telephone (area code, number, extension) 517-824-4240		
9d. E-Mail Address banghaet@ega.msu.edu		
9e. Date report submitted (MM/DD/YYYY) 12/07/2021	10. Agency use only	

Federal Financial Report

(Follow form instructions)

OMB Approval Number: 4040-0014

Expiration Date: 03/28/2022

1. Federal Agency and Organizational Element to Which Report is Submitted US Agency for Int'l Development		2. Federal Grant or Other Identifying Number Assigned by Federal Agency (To report multiple grants, use FFR Attachment) AID-OAA-A-15-0-0056	
3. Recipient Organization (Name and complete address including Zip code) Recipient Organization Name: Michigan State University Street 1: Contract & Grant Administration Street 2: 426 Auditorium Road, Room 2 City: East Lansing County: State: MI Province: USA: United States ZIP Postal Code: 48824-1046			
4a. DUNS Number 193247145	4b. EIN 38-6005934	5. Recipient Account Number or Identifying Number (To report multiple grants, use FFR Attachment) RC10 5463	
6. Report Type a Quarterly a Semi-Annual a Annual X Final	7. Basis of Accounting X Cash a Accrual	8. Report/Grant Period From: 9/30/2015 To: 9/30/2021	9. Reporting Period End Date 9/30/2021
10. Transactions		Cumulative	
(Use lines a-c for single grant reporting)			
Federal Cash (To report multiple grants, also use FFR Attachment)			
a. Cash Receipts		\$ 8,473,859.30	
b. Cash Disbursements		\$ 8,473,859.30	
c. Cash on Hand (line a minus b)		\$ -	
(Use lines d-h for single grant reporting)			
Federal Expenditures and Unobligated Balance			
d. Total Federal funds authorized		\$ 8,473,859.30	
e. Federal share of expenditures		\$ 8,473,859.30	
f. Federal share of unfunded obligations		\$ -	
g. Total Federal share (sum of lines e and f)		\$ 8,473,859.30	
h. Unobligated balance of Federal funds (line d minus g)		\$ -	
Nongrant Share			
i. Total recipient share required		\$ 137,221.00	
j. Recipient share of expenditures		\$ 137,221.00	
k. Remaining recipient share to be provided (line i minus j)		\$ -	
Program Income			
l. Total Federal program income earned		\$ -	
m. Program income expended in accordance with the deduction alternative		\$ -	
n. Program income expended in accordance with the addition alternative		\$ -	
o. Unexpended program income (line i minus line m or line n)		\$ -	
11. Indirect Expenses			
a. Type	b. Rate	c. Period From	d. Period To
Predefined	20.00%	9/30/2015	9/30/2021
			e. Amount Charged
			\$253,280.33
			f. Federal Share
			\$253,280.33
g. Totals			\$253,280.33
12. Remarks: Attach any explanations deemed necessary or information required by Federal sponsoring agency in compliance with governing legislation.			
13. Certification: By signing this report, I certify that it is true, complete, and accurate to the best of my knowledge and belief; that the report is true, complete, and accurate; and that expenditures, disbursements and cash receipts are for the purpose and objectives set forth in the terms and conditions of the federal award. I am aware that any false, fictitious, or fraudulent information, or the omission of any material fact, may subject me to criminal, civil, or administrative penalties provided, false statements, false claims or otherwise. (U.S. Code, Title 18, Section 1001 and Title 31, Sections 3729-3730 and 3801-3812)			
a. Name and Title of Authorized Certifying Official First Name: Jeffrey Middle Name: Last Name: Sanghai Title: Contract & Grant Administrator			
b. Signature of Authorized Certifying Official 		c. Telephone (Area code, number and extension) 517-334-4240	
d. Email Address csghai@usaid.gov		e. Date Report Submitted 12/19/2021	14. Agency use only

Standard Form 425

Paperwork Burden Statement

According to the Paperwork Reduction Act, as amended, no persons are required to respond to a collection of information unless it displays a valid OMB Control Number. The valid OMB control number for this information collection is 4040-0014. Public reporting burden for this collection of information is estimated to average 1 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: US Department of Health & Human Services, OHSI/OPRA, 200 Independence Ave., SW, Suite 205C, Washington DC 20201. Attention: PRA Reports Clearance Office



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